

EXHIBIT 2C

WAVE 1
EXHIBIT

C

4 IN RE: ETHICON, INC., § MASTER FILE
PELVIC REPAIR SYSTEM PRODUCTS § NO. 2:12-MD-02327
5 LIABILITY LITIGATION §
§
6 § MDL NO. 2327
THIS DOCUMENT RELATES TO: §
7 DIANNE M. BELLEW, § JOSEPH R. GOODWIN
§ US DISTRICT JUDGE
8 Case No. 2:13-cv-22473 §
§

9 -----
10 - - -
11 November 10, 2014
12 - - -
13 Videotaped deposition of PROF. DR. MED. UWE
14 KLINGE, held at Quellenhof Hotel, Monheimsallee
15 52, 52062, Aachen, Germany, commencing at
16 9:04 a.m., on the above date, before Tami Cline,
17 Registered Merit Reporter, Certified Realtime
18 Reporter.

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		Page 2	Page 4
1	APPEARANCES:		
2	ANDERSON LAW OFFICES, LLC		E X H I B I T S (CONTINUED)
3	BY: BENJAMIN HOUSTON ANDERSON, ESQUIRE		(ATTACHED)
4	1360 West 9th Street		EXHIBIT NO. PAGE
5	Suite 215		Klinge Trial Article entitled "Long-term 165
6	Cleveland, Ohio 44113		Deposition 5 outcome and quality of life
7	216-592-8384		after open incisional hernia
8	Ben@andersonlawoffices.net		repair - light versus
9	Representing the Plaintiffs		heavyweight meshes"
10	THOMAS COMBS & SPANN, PLLC		Klinge Trial Article entitled "Bias-Variation 169
11	BY: DAVID B. THOMAS, ESQUIRE		Deposition 6 Dilemma Challenges Clinical
12	300 Summers Street		Trials: Inherent Limitations of
13	Suite 1380		Randomized Controlled Trials and
14	Charleston, West Virginia 25301		Meta-Analyses Comparing Hernia
15	Dthomas@tcspllc.com		Therapies"
16	BUTLER SNOW, LLP		Klinge Trial Article entitled "Prospective, 173
17	BY: CHAD R. HUTCHINSON, ESQUIRE		Deposition 7 Long-Term Comparison of Quality
18	1020 Highland Colony		of Life in Laparoscopic Versus
19	Renaissance at Colony Park, Suite 1400		Open Ventral Hernia Repair"
20	Ridgeland, Mississippi 39157		Plaintiff's P0036 PowerPoint presentation 41
21	601-948-5711		entitled "Stand & Deliver -
22	Chad.hutchinson@butlersnow.com		Pelvic Floor Repair"
23	Representing Johnson & Johnson and Ethicon		Plaintiff's PLT0067 Article entitled 26
24	ALSO PRESENT:		"Complications from
	Gregory Fields, Videographer		vaginally placed mesh in
	Julie Filarski, Anderson Law Offices, LLC		pelvic reconstructive
	Michael Kauffmann, Precision Trial Solutions		surgery"
	---		Plaintiff's PLT0260 Article entitled "Impact of 49
	IN D E X		Polymer Pore Size on the
	---		Interface Scar Formation in
	Testimony of: PROF. DR. MED. UWE KLINGE		a Rat Model"
	DIRECT EXAMINATION BY MR. ANDERSON..... 10		Plaintiff's PLT0271 Article entitled "The 51
	CROSS-EXAMINATION BY MR. THOMAS..... 82		lightweight and large porous
	REDIRECT EXAMINATION BY MR. ANDERSON..... 192		concept for hernia repair"
	---		Plaintiff's PLT0697 Article entitled "Elongation 60
	E X H I B I T S		of textile pelvic floor
	(ATTACHED)		implants under load is
	EXHIBIT NO. PAGE		related to complete loss of
	Klinge Trial Article entitled "New Objective 121		effective porosity, thereby
	Deposition 1 Measurement to Characterize the		favoring incorporation in
	Porosity of Textile Implants,"		scar plates"
	Bates stamped DX31026.1 through		
	DX31026.8		
	Klinge Trial Article entitled "Synthetic and 126		
	Deposition 2 biodegradable prostheses in		
	pelvic floor surgery," Bates		
	stamped DX3036.1 through		
	DX3036.11		
	Klinge Trial Article entitled "The biology 130		
	Deposition 3 behind fascial defects and the		
	use of implants in pelvic organ		
	prolapse repair," Bates stamped		
	DX3036.0.1 through DX3036.10		
	Klinge Trial Ethicon Final Report, PSE 141		
	Deposition 4 Accession No. 00-0035, An		
	Exploratory 91-day Tissue		
	Reaction Study of		
	Polypropylene-based Surgical		
	mesh in Rates (PSE ACC. NO.		
	00-0035)		

		Page 6	Page 8		
1	E X H I B I T S		1	---	
2	(CONTINUED)		2	DEPOSITION SUPPORT INDEX	
3	EXHIBIT NO.	PAGE	3	---	
3	Plaintiff's P1679	PowerPoint presentation entitled "Factors related to mesh shrinkage - What do we know? A review of literature and internal studies"	54	4	PAGE
6	Plaintiff's P2995	PowerPoint presentation entitled "Mesh Properties - How important are they?"	72	5	REPORTER'S CERTIFICATE..... 220
7	Plaintiff's P3184	Letter to Quentin from Christoph Walther, Bates stamped HMESH_ETH_00379723	199	6	INSTRUCTIONS TO WITNESS..... 221
9	Plaintiff's P3355	English Translation of Plaintiff's Exhibit 3354, Patent for PVDF mesh	196	7	WITNESS ERRATA..... 222
10	Plaintiff's P3356	Page 20 of 1386 from Howard Jordi's expert report containing photographs	30	8	WITNESS ACKNOWLEDGEMENT..... 223
11	Plaintiff's P3357	Document Bates stamped Demonstrative ETH-01755	64	9	LAWYER'S NOTES..... 224
14	Plaintiff's P3358	PowerPoint slide titled "Foreign Body Reaction: More Foreign Body = More Inflammation," Bates stamped P1005 ETH.MESH.02341454	17	10	
19	Plaintiff's P3359	PowerPoint slide entitled "Patient Injury Due to Mesh Inflammation and Contraction"	32	11	
21	Plaintiff's P3360	PowerPoint slide, a blowup referencing PLT0697 "Elongation of textile pelvic floor implants under load is related to complete loss of effective porosity, thereby favoring incorporation in scar plates"	62	12	
24			13		
24			14		
24			15		
24			16		
24			17		
24			18		
24			19		
24			20		
24			21		
24			22		
24			23		
24			24		
		Page 7	Page 9		
1	E X H I B I T S		1	---	
2	(CONTINUED)		2	THE VIDEOGRAPHER: We are now on the record.	
2	(ATTACHED)		3	My name is Gregory Fields. I'm the videographer	
3	EXHIBIT NO.	PAGE	4	for Golkow Technologies. Today's date is	
3	Plaintiff's P3361	PowerPoint slide entitled "Pores Collapse Under Tension," referencing P2995, ETH.MESH.05237872, PLT 0697, P1452 - ETH.MESH.000007	74	5	11/10/2014, and the time is 9:04 a.m. This video
6	Plaintiff's P3362	PowerPoint slide entitled "Prolift Unsafe/Defective Mesh Design"	79	6	deposition is being held in Aachen, Germany, in
8	Defendant's DX30064	Article entitled "Classification of biomaterials and their related complications in abdominal wall hernia surgery"	133	7	the matter of In Re: Pelvic mesh, for the
11		(RETAINED BY MR. ANDERSON)		8	Superior Court of New Jersey, Atlantic County.
12	Plaintiff's P3363	Prolene suture	20	9	The deponent is Uwe Klinge. Counsel will be
13	Plaintiff's P3364	240 meters of polypropylene	21	10	noted on the stenographic record. The court
14	Plaintiff's P3365	Basketball net	57	11	reporter is Tami Cline and will now swear in the
15			12	witness.	
16			13	MR. THOMAS: The court reporter noted that	
17			14	the taped deposition was being taken in the	
18			15	Superior Court of New Jersey. I thought this was	
19			16	an MDL deposition.	
20			17	THE VIDEOGRAPHER: I'm sorry. I had that as	
21			18	a --	
22			19	MR. ANDERSON: MDL deposition.	
23			20	THE VIDEOGRAPHER: This is the MDL?	
24			21	MR. ANDERSON: Yeah.	
24			22	THE VIDEOGRAPHER: I apologize.	
24			23	MR. THOMAS: And only the MDL. It's not	
24			24	cross-noticed in New Jersey.	

Page 10	Page 12
<p>1 MR. ANDERSON: It's MDL.</p> <p>2 THE VIDEOGRAPHER: Okay. Okay.</p> <p>3 THE COURT REPORTER: Would you raise your</p> <p>4 right hand, please.</p> <p>5 Do you swear or affirm the testimony you give</p> <p>6 in this cause will be the truth, the whole truth</p> <p>7 and nothing but the truth?</p> <p>8 THE WITNESS: I swear.</p> <p>9 THE COURT REPORTER: You can put your hand</p> <p>10 down.</p> <p>11 PROF. DR. MED. UWE KLINGE, called as a</p> <p>12 witness by the Plaintiff, having been first duly</p> <p>13 sworn, testified as follows:</p> <p>14 DIRECT EXAMINATION</p> <p>15 BY MR. ANDERSON:</p> <p>16 Q. Good morning, Dr. Klinge.</p> <p>17 A. Good morning.</p> <p>18 Q. Dr. Klinge, please tell the jury what your</p> <p>19 profession is.</p> <p>20 A. I'm an abdominal surgeon and a biomaterial</p> <p>21 researcher.</p> <p>22 Q. Where do you work, Dr. Klinge?</p> <p>23 A. I'm working at the University of Aachen.</p> <p>24 Q. And is that Aachen, Germany?</p>	<p>1 and some years later on I got specified as an</p> <p>2 abdominal surgeon.</p> <p>3 Q. Tell the jury a little bit about your</p> <p>4 practice of abdominal surgery.</p> <p>5 A. While working at this surgical department, I</p> <p>6 performed some thousands of operations, mainly done</p> <p>7 for diseases of the abdominal cavity of the intestine</p> <p>8 of the abdominal wall, but it covers almost all parts</p> <p>9 of the body.</p> <p>10 Q. Have you used synthetic surgical mesh in your</p> <p>11 surgical practice?</p> <p>12 A. Yes, I did.</p> <p>13 Q. Did you use hernia meshes in your surgical</p> <p>14 practice that were manufactured by Ethicon?</p> <p>15 A. Yes, I did.</p> <p>16 Q. Doctor, what caused you to study the</p> <p>17 biomaterial science of surgical meshes?</p> <p>18 A. When we started to use surgical meshes in the</p> <p>19 beginning of the '90s, we got aware that we have to</p> <p>20 face several complications that are related with</p> <p>21 these mesh materials, mainly at the occasion of some</p> <p>22 revision operations where we saw what happens to</p> <p>23 these meshes after getting incorporated; and we</p> <p>24 wanted to learn more about these meshes to avoid</p>
<p>1 A. It's Aachen, Germany.</p> <p>2 Q. And is that where we are today?</p> <p>3 A. Exactly.</p> <p>4 Q. Please tell the jury a little bit about</p> <p>5 Aachen University Hospital.</p> <p>6 A. It's a large teaching and research hospital,</p> <p>7 and it is -- it has an extended research center</p> <p>8 dealing with medical devices, the development of</p> <p>9 medical devices.</p> <p>10 Q. And would those medical devices include</p> <p>11 surgical meshes like the Prolift mesh?</p> <p>12 A. Yes.</p> <p>13 Q. And before we go through the issues in this</p> <p>14 case, would you please just tell the jury briefly</p> <p>15 about your education and training as a surgeon?</p> <p>16 A. I started my medical training 1977 at this</p> <p>17 university, and when I finished it, then I started to</p> <p>18 work in the surgical department at this university</p> <p>19 for almost now -- almost 30 years. Yeah.</p> <p>20 Q. And did you do a surgical residency?</p> <p>21 A. Yes.</p> <p>22 Q. What years did you do a surgical residency?</p> <p>23 A. It started in 1985, and I worked specified as</p> <p>24 abdominal surgeon -- as a general surgeon in 1993,</p>	<p>1 these complications.</p> <p>2 Q. And when did you first begin that work?</p> <p>3 A. We started to think about it in the beginning</p> <p>4 of the '90s, and the research project really started</p> <p>5 in 1994.</p> <p>6 Q. And as part of your work in looking at the</p> <p>7 biomaterial science of surgical meshes and trying to</p> <p>8 relate those to complications, did you work as a</p> <p>9 consultant for Ethicon?</p> <p>10 A. Yes, indeed. When we decided to study meshes</p> <p>11 and wanted to know what is the impact of the meshes</p> <p>12 to the damage in the tissue, it was necessary to</p> <p>13 collaborate with the manufacturer, because for these</p> <p>14 research, you need a lot of modifications. You need</p> <p>15 a lot of different designs to find out what is the</p> <p>16 impact of a specific design to the tissue response.</p> <p>17 And we have been very happy to find Ethicon as a</p> <p>18 partner in this research who, during the following</p> <p>19 ten years, supplied us with a lot of these meshes and</p> <p>20 a lot of modifications so that we can do all these</p> <p>21 studies.</p> <p>22 Q. And was this collaboration between Aachen</p> <p>23 University Hospital, where you are here in Aachen,</p> <p>24 and Ethicon?</p>

Page 14	Page 16
1 A. Yes.	1 structure as for Prolene Soft.
2 Q. Okay. Dr. Klinge, all of your opinions today	2 Q. So Prolene, Prolene Soft and Gynemesh PS, is
3 will need to be to a reasonable degree of medical and	3 it your testimony they are all brand names for
4 scientific certainty. Do you understand that?	4 polypropylene mesh made by Ethicon?
5 A. Yes.	5 A. Yes.
6 Q. Have you published articles in the	6 Q. Okay. What is the mesh material that's in
7 peer-reviewed medical literature that relate to the	7 the Prolift device?
8 safety of surgical meshes either for the abdomen or	8 A. It is polypropylene.
9 the pelvic floor?	9 Q. And what is the brand name from Ethicon for
10 A. Yes, I did.	10 this polypropylene in the Prolift device?
11 Q. How many times?	11 A. It's Gynemesh PS.
12 A. With the specific topic of surgical meshes,	12 Q. Okay. Have you reviewed and do you rely upon
13 it's more than 100.	13 Ethicon internal documents and depositions of Ethicon
14 Q. Have you written books and book chapters that	14 witnesses that you reviewed over the course of this
15 relate to the safety of surgical meshes for both the	15 case in arriving at your opinions that you are going
16 abdomen and the pelvic floor?	16 to offer here today?
17 A. Yes, I did.	17 A. Yes.
18 Q. And on how many times?	18 Q. With regard to the Prolift, are you familiar
19 A. About 50.	19 with the weight and surface area, the weave pattern
20 Q. Have you been asked to speak at conferences	20 and the pore size --
21 around the world on the topic of surgical mesh	21 A. Yes.
22 complications and safer mesh design for the abdomen	22 Q. -- of Prolift mesh?
23 and the pelvic floor?	23 A. I'm sorry.
24 A. Yes, I have been, and I'm still.	24 Q. All right.
Page 15	Page 17
1 Q. Have you been asked by Ethicon to speak as an	1 A. Yes, I am.
2 invited lecturer at conferences sponsored by Ethicon?	2 Q. Generally speaking, how is the Prolift
3 A. Yes.	3 supposed to function?
4 Q. On how many occasions?	4 A. It is supposed to function as a flat layer
5 A. Several dozens.	5 reinforcing the tissue and the pelvic floor.
6 Q. Have you been invited by Ethicon to speak	6 Q. Dr. Klinge, I would like to talk to the jury
7 directly to urogynecologists and urologists regarding	7 now about the way the tissue in our bodies reacts to
8 surgical meshes for the pelvic floor?	8 a foreign substance like polypropylene. Now, with
9 A. Yes, I was.	9 your help and at your request, did we prepare some
10 Q. Doctor, what is Prolene mesh?	10 slides for the jury today?
11 A. Prolene mesh is the brand name of a mesh, a	11 A. Yes.
12 plastic net made of polypropylene fibers.	12 Q. And would you feel that those would be
13 Q. And is there a particular manufacturer that	13 helpful to you as we are talking about some of your
14 uses the brand name Prolene?	14 opinions with the jury?
15 A. It's a brand name from Ethicon.	15 A. Yes.
16 Q. Are you familiar with the term "Prolene Soft	16 MR. THOMAS: Let's go off the record a
17 Mesh"?	17 second, please.
18 A. Yes.	18 THE VIDEOGRAPHER: We are off the record.
19 Q. And what is Prolene Soft Mesh?	19 The time is 9:13 a.m.
20 A. It is, again, a brand name from a mesh from	20 (A recess was taken from 9:13 a.m. until 9:14 a.m.)
21 Ethicon made of polypropylene fibers.	21 THE VIDEOGRAPHER: We are back on the record.
22 Q. And you're familiar with the word -- the mesh	22 The time is 9:14 a.m.
23 Gynemesh PS?	23 - - -
24 A. Yes. It is -- it is the same textile	24 (Plaintiff's Demonstrative Exhibit No. P3358,

Page 18	Page 20
<p>1 PowerPoint slide titled "Foreign Body Reaction: More</p> <p>2 Foreign Body = More Inflammation," Bates stamped</p> <p>3 P1005 ETH.MESH.02341454, marked for identification.)</p> <p>4 - - -</p> <p>5 BY MR. ANDERSON:</p> <p>6 Q. Doctor, I'm showing you the first slide,</p> <p>7 which is a demonstrative exhibit, which we have gone</p> <p>8 ahead and labeled as Plaintiff's Exhibit P3358. Is</p> <p>9 this slide entitled, "Foreign Body Reaction," a slide</p> <p>10 that you helped prepare for the jury today?</p> <p>11 A. Yes.</p> <p>12 Q. What does foreign body reaction refer to?</p> <p>13 A. Foreign body reaction mainly consists of an</p> <p>14 inflammatory reaction and a scar reaction. And if</p> <p>15 you -- assume you get a splinter or foreign body into</p> <p>16 your tissues. The body tries to get rid of it, and</p> <p>17 if they -- if the body is not able to get rid of this</p> <p>18 foreign body, it's sent a lot of white blood cells to</p> <p>19 this to build a wall to protect the surrounding</p> <p>20 tissue from this foreign body. And this</p> <p>21 inflammatory -- these inflammatory cells are then</p> <p>22 surrounded by dense scar tissue.</p> <p>23 Q. And when we see on this slide "more foreign</p> <p>24 body equals more inflammation" -- you have put that</p>	<p>1 anterior implant.</p> <p>2 Q. Doctor, did I ask you to bring with you to</p> <p>3 your testimony today a Prolene suture?</p> <p>4 A. Yes.</p> <p>5 MR. ANDERSON: And, Counsel, for purposes of</p> <p>6 the record, it's a demonstrative exhibit, which</p> <p>7 we have premarked as Plaintiff's Exhibit P3363.</p> <p>8 - - -</p> <p>9 (Plaintiff's Exhibit No. P3363, Prolene</p> <p>10 suture, was marked for identification.)</p> <p>11 - - -</p> <p>12 BY MR. ANDERSON:</p> <p>13 Q. Doctor, is this the Prolene suture you</p> <p>14 brought here to the deposition today?</p> <p>15 A. Yes. Exactly.</p> <p>16 Q. Can you please first show the Prolene suture</p> <p>17 to the jury? If you would just lay it on that piece</p> <p>18 of paper so the -- our kind videographer here can</p> <p>19 pick up on that.</p> <p>20 A. (Complying.)</p> <p>21 Q. Thank you.</p> <p>22 Now, Doctor, you have placed sutures like</p> <p>23 this in patients?</p> <p>24 A. Yes. This is a typical suture we are using</p>
Page 19	Page 21
<p>1 there. Why have you put that there for the jury?</p> <p>2 A. Sorry?</p> <p>3 Q. "More foreign body equals more inflammation,"</p> <p>4 why have we put that there? Why is that significant</p> <p>5 to your opinions, Doctor?</p> <p>6 A. Yeah. It was one of our -- or it was</p> <p>7 confirmed by all of our studies that, of course, the</p> <p>8 more foreign body you have, the more inflammation you</p> <p>9 have. The more surface you have, the more</p> <p>10 inflammation you have. So if you have two splinters,</p> <p>11 you will have more inflammation than if it is only</p> <p>12 one.</p> <p>13 Q. Doctor, I believe by this time in the trial</p> <p>14 that the jury would have already seen a Prolift</p> <p>15 anterior mesh. I -- we have one there on the slide.</p> <p>16 Did I ask you to calculate the amount of</p> <p>17 polypropylene fiber that is woven into a Prolift</p> <p>18 anterior mesh?</p> <p>19 A. Yes, I did.</p> <p>20 Q. And please tell the jury how much</p> <p>21 polypropylene suture material is in a Prolift</p> <p>22 anterior mesh.</p> <p>23 A. So it is -- it is about 240 meters of</p> <p>24 polypropylene fiber that is used in the Prolift</p>	<p>1 in the OR, but usually we made some knots about it</p> <p>2 and we removed the rest of the fibers. So, actually,</p> <p>3 we left 1 to 2 centimeters of this suture in the body</p> <p>4 when we made a stitch with this material.</p> <p>5 Q. So given that you trim this after you do the</p> <p>6 stitch, show the jury, if you would, how much</p> <p>7 polypropylene stitch is left.</p> <p>8 A. So, of course, it depends from thickness of</p> <p>9 the tissue, but usually it's not more than this.</p> <p>10 Q. What is that?</p> <p>11 A. What remains in the tissue after --</p> <p>12 Q. About 2 inches?</p> <p>13 A. An inch is 2.5 centimeters, so it is -- it is</p> <p>14 less than one inch.</p> <p>15 Q. Okay. By way of example, Doctor, did I ask</p> <p>16 you to measure -- you said there was 240 meters of</p> <p>17 polypropylene material in an anterior mesh?</p> <p>18 A. Yes.</p> <p>19 - - -</p> <p>20 (Plaintiff's Exhibit No. P3364, 240 meters of</p> <p>21 polypropylene, marked for identification.)</p> <p>22 - - -</p> <p>23 BY MR. ANDERSON:</p> <p>24 Q. I will mark this as Plaintiff's</p>

Page 22	Page 24
<p>1 Exhibit P3364. Did I ask you to measure out 240 2 meters of polypropylene? 3 A. Yes. I -- 4 Q. Could you, please -- and did you measure that 5 yourself? 6 A. Yeah. I did it myself, and I actually walked 7 20 times in my room or at my house -- 8 Q. Okay. 9 A. -- to get this -- the length of this suture 10 material. 11 Q. If you would just lay that on the piece of 12 material next to it. 13 A. Yeah. 14 Q. Now, Doctor, we're not as familiar in the 15 United States with the metric system. How many yards 16 of material does 240 meters relate to? 17 A. It is equal to 260 yards. 18 Q. And you know in the US we play football, and 19 a football field is 100 yards long. So is this more 20 than two and a half football fields of material 21 that's woven into a Prolene anterior mesh? 22 A. Exactly. Or if you don't play football, it 23 is three times the height of the Statue of Liberty in 24 New York.</p>	<p>1 A. Yes. 2 Q. Just briefly tell the jury in your own words 3 what mesh contraction or mesh shrinkage is. 4 A. When we are talking about mesh shrinkage, we 5 usually are thinking of the contraction of the scar 6 tissue around the mesh. 7 Q. And is scar tissue -- is there another -- is 8 fibrosis also another word for scar tissue? 9 A. Yes. Fibrosis is -- the fibrosis around the 10 mesh is usually the scar tissue. 11 Q. So if this piece of paper is the mesh as it's 12 in the body, can you explain to the jury what we're 13 talking about in terms of mesh shrinkage or 14 contraction if that's the implant and the black here 15 is -- the table is the tissue? 16 A. When the mesh is usually incorporated into 17 the scar tissue, and we know that scar contracts. It 18 lose a lot of water, and, therefore, when the scar is 19 contracting, it is pushing together the implant like 20 this. It can be up to 90 percent that the mesh 21 material is reduced by this contraction of the scar. 22 Q. Have you published in the peer-reviewed 23 literature on the subject of mesh shrinkage and 24 contraction and the resulting clinical consequence to</p>
<p style="text-align: center;">Page 23</p> <p>1 Q. Okay. All right. Thank you. 2 Doctor, do you have an opinion to a 3 reasonable degree of medical and scientific certainty 4 as to whether there will be a different amount of 5 foreign body reaction and inflammation in a patient's 6 tissues to less than one inch of suture material of 7 polypropylene versus more than two and a half 8 football fields of polypropylene material? Do you 9 have an opinion? 10 A. Yes. 11 Q. And what is that opinion? 12 A. If you place this huge amount of material in 13 a comparatively small area, you will have a 14 significantly higher intensity and amount of 15 inflammation and scar tissue as a reaction to this 16 huge amount of material. 17 Q. Okay. Doctor, we can put those to the side 18 for the moment. 19 I would like to now -- sorry. I would now 20 like to talk to you about the relationship between 21 this foreign body reaction to polypropylene mesh and 22 a concept known as mesh contraction or mesh 23 shrinkage. Are you familiar with those terms, mesh 24 shrinkage or mesh contraction?</p>	<p style="text-align: center;">Page 25</p> <p>1 patients? 2 A. Yes, I did. 3 Q. How many publications over what period of 4 time relate to mesh shrinkage and mesh contraction 5 that you have authored? 6 MR. THOMAS: Objection, without more 7 specificity into what area of the body. 8 BY MR. ANDERSON: 9 Q. Doctor, have you published in the 10 peer-reviewed literature on the subject of mesh 11 shrinkage and contraction of polypropylene meshes, 12 like the Prolift mesh, resulting in clinical 13 consequences to patients? 14 A. Yes. 15 MR. THOMAS: Same objection. 16 BY MR. ANDERSON: 17 Q. How many times have you done that, Doctor? 18 A. It's more than 50. 19 Q. Doctor, in terms of inflammatory response and 20 this foreign body reaction that we have been talking 21 to, will that -- will there be any difference between 22 a surgical mesh implanted, for instance, in the 23 abdominal wall and these principles versus a surgical 24 mesh implanted in the pelvic floor?</p>

Page 26	Page 28
<p>1 MR. THOMAS: Objection; foundation.</p> <p>2 THE WITNESS: The wound contraction is not</p> <p>3 restricted to the abdominal wall. It happens in</p> <p>4 the entire body. The foreign body responds. The</p> <p>5 scarring around a foreign body happens in every</p> <p>6 part of the body, and in this regard the response</p> <p>7 of the tissue to the -- to a mesh, it's quite</p> <p>8 similar whether it is in the pelvic floor or</p> <p>9 whether it's in the abdominal cavity.</p> <p>10 BY MR. ANDERSON:</p> <p>11 Q. Doctor, I now want to explain to the jury</p> <p>12 what the consequences to the patient are of severe</p> <p>13 inflammation and contraction of polypropylene mesh</p> <p>14 like Prolift. Okay?</p> <p>15 A. Yes.</p> <p>16 - - -</p> <p>17 (Plaintiff's Exhibit No. PLT0067, Article</p> <p>18 entitled "Complications from vaginally placed mesh in</p> <p>19 pelvic reconstructive surgery", was marked for</p> <p>20 identification.)</p> <p>21 - - -</p> <p>22 BY MR. ANDERSON:</p> <p>23 Q. I'm handing you what has been marked as</p> <p>24 Plaintiff's Exhibit 0067. It is PLT0067.</p>	<p>1 MR. THOMAS: Just note my objection to this</p> <p>2 before you show the jury what the picture is</p> <p>3 until we have an adequate foundation for the jury</p> <p>4 to see the picture.</p> <p>5 BY MR. ANDERSON:</p> <p>6 Q. And you reviewed this article in coming to</p> <p>7 your opinions in this case?</p> <p>8 A. Yes.</p> <p>9 Q. And does this article involve the Prolift</p> <p>10 mesh?</p> <p>11 A. Yes.</p> <p>12 Q. And if we're looking at this image contained</p> <p>13 within the article, what are we looking at here,</p> <p>14 Doctor?</p> <p>15 A. It is showing the explanted mesh material</p> <p>16 that is in -- taken off in several parts, and you see</p> <p>17 that it is incorporated into a lot of scar tissue,</p> <p>18 that it is deformed, that it's not laying very flat</p> <p>19 in this area.</p> <p>20 MR. THOMAS: Just show --</p> <p>21 THE WITNESS: It's hard to identify the</p> <p>22 textile structure in this compound of scar.</p> <p>23 MR. THOMAS: I just want to show my</p> <p>24 continuing objection for lack of foundation.</p>
<p>1 MR. THOMAS: This has a sticky on it. Is</p> <p>2 that yours?</p> <p>3 MR. ANDERSON: What I have done for you,</p> <p>4 Counsel, is on every one of these documents,</p> <p>5 since they're multipaged, to make it easier for</p> <p>6 you to reference them, I flagged the pages for</p> <p>7 you.</p> <p>8 MR. THOMAS: Thank you.</p> <p>9 MR. ANDERSON: You're welcome.</p> <p>10 BY MR. ANDERSON:</p> <p>11 Q. Do you recognize this article as something</p> <p>12 you reviewed in arriving at your opinions in this</p> <p>13 case?</p> <p>14 A. Yes.</p> <p>15 Q. And it says -- is this article from the</p> <p>16 International Urogynecological Journal in 2009</p> <p>17 significant to your opinions in this case?</p> <p>18 A. Yes, it is.</p> <p>19 Q. If you will please turn with me to page 529.</p> <p>20 MR. ANDERSON: And if you'll highlight --</p> <p>21 Michael, if you'll highlight the bottom right</p> <p>22 image.</p> <p>23 BY MR. ANDERSON:</p> <p>24 Q. Doctor --</p>	<p>1 MR. ANDERSON: Noted.</p> <p>2 BY MR. ANDERSON:</p> <p>3 Q. As a hernia surgeon, did you remove</p> <p>4 contracted polypropylene meshes from patients?</p> <p>5 A. Yeah. We did a lot. And the appearance of</p> <p>6 these meshes are completely similar to this. We</p> <p>7 have -- in these contracted meshes, we have this huge</p> <p>8 amount of scar tissue. The advantage in the</p> <p>9 abdominal wall is that we are able to explant them in</p> <p>10 total and, whereas in this area, it usually is taken</p> <p>11 off in parts.</p> <p>12 Q. And you say, "in this area." You removed</p> <p>13 mesh from the pelvic floor?</p> <p>14 A. Yes.</p> <p>15 Q. Did you have an opportunity to review</p> <p>16 Dr. Howard Jordi's expert report in this case?</p> <p>17 A. Yes.</p> <p>18 Q. Did you see photos in his report of mesh that</p> <p>19 had been taken out of Ms. Bellew?</p> <p>20 A. Yes.</p> <p>21 Q. And did you rely on those photos in his</p> <p>22 report in arriving at your opinions here today?</p> <p>23 A. Yes.</p> <p>24 MR. THOMAS: Objection. To my knowledge,</p>
	Page 29

Page 30	Page 32
<p>1 the -- any specific causation testimony of 2 Ms. Bellew is not contained in his report. Am I 3 incorrect?</p> <p>4 MR. ANDERSON: We're not going to talk about 5 causation.</p> <p>6 MR. THOMAS: Okay. Show my objection to any 7 plaintiff-specific testimony by Dr. Klinige.</p> <p>8 MR. ANDERSON: I'll show your objection.</p> <p>9 - - -</p> <p>10 (Plaintiff's Exhibit No. P3356, Page 20 of 11 1386 from Howard Jordi's expert report containing 12 photographs, was marked for identification.)</p> <p>13 - - -</p> <p>14 BY MR. ANDERSON:</p> <p>15 Q. I'm handing you what's been premarked as 16 Plaintiff's Exhibit 3356. Is that one of the 17 photographs that you saw from Dr. Jordi's report of 18 explanted mesh from Ms. Bellew?</p> <p>19 A. Yes, it is.</p> <p>20 Q. Was this image significant to your opinions 21 in this case?</p> <p>22 A. Yes.</p> <p>23 Q. Can you please explain the significance of 24 that image in relation to what we just -- what the</p>	<p>1 compare to contracted mesh removed due to 2 complications like we've seen in these -- in these 3 recent photographs from the Blandon article as well 4 as this from Ms. Bellew?</p> <p>5 A. The mesh, when it's taken out of the box, 6 usually is very soft, pliable, flexible, whereas a 7 mesh that is integrated into this scar tissue usually 8 is rigid, stiff, not flexible, not stretchable any 9 longer; and, therefore, it is going to be in sharp 10 contrast to the properties of the surrounding tissue.</p> <p>11 Q. Doctor, did you prepare a slide for the jury 12 regarding mesh inflammation and contraction and their 13 relation to consequences for the patient?</p> <p>14 A. Yes.</p> <p>15 - - -</p> <p>16 (Plaintiff's Demonstrative Exhibit No. P3359, 17 PowerPoint slide entitled "Patient Injury Due to Mesh 18 Inflammation and Contraction", was marked for 19 identification.)</p> <p>20 - - -</p> <p>21 BY MR. ANDERSON:</p> <p>22 Q. I'm showing you what we have marked as 23 Plaintiff's Exhibit P3359. Is that the slide?</p> <p>24 A. Yes.</p>
Page 31	Page 33
<p>1 jury just saw?</p> <p>2 A. This image --</p> <p>3 MR. THOMAS: Excuse me. Let me place my 4 objection. I object to this because it is not a 5 disclosed opinion in the report that Ben here -- 6 that's at issue in this deposition and also 7 because this witness is designated on general 8 causation issues and not on plaintiff-specific 9 issues.</p> <p>10 BY MR. ANDERSON:</p> <p>11 Q. Does the appearance of Ms. Bellew's 12 contracted mesh in -- does the appearance of the mesh 13 in -- from Dr. Jordi's report -- what do you see from 14 that -- from that image, sir?</p> <p>15 A. On this photograph you see the folding of a 16 mesh that is incorporated into very big amount of 17 scar tissue, and it is a confirmation that this 18 phenomenon is not limited to the abdominal wall, but 19 it happens in every part of the body.</p> <p>20 Q. Now, Doctor, you have seen the Prolift 21 anterior mesh as it comes out of the box? Have you 22 seen that?</p> <p>23 A. Yes.</p> <p>24 Q. How does the Prolift mesh out of the box</p>	<p>1 Q. Okay.</p> <p>2 MR. ANDERSON: If you could just bring in the 3 first bullet points.</p> <p>4 MR. THOMAS: Just show my objection to this 5 demonstrative and testimony about this because 6 the patient has not been designated for the 7 quantitative risks of complications in the pelvic 8 floor.</p> <p>9 BY MR. ANDERSON:</p> <p>10 Q. Doctor, if we look here to these first two 11 bullet points, can you tell us why you created these 12 for the jury?</p> <p>13 A. One of our important findings in these years 14 of research together with Ethicon was that this mesh 15 inflammation, this inflammatory region around the 16 foreign body, it's a permanent one. It is -- it 17 doesn't stop after three weeks or four weeks, but it 18 stays there as a chronic wound until the end of the 19 life of the patient; and this chronic wound leads to 20 a permanent tissue irritation.</p> <p>21 In some patients there's always some sort of 22 scarring that is protecting the surrounding tissues 23 from the foreign body, but in some patients this 24 scarring is very, very severe; and it leads that</p>

Page 34	Page 36
<p>1 almost all the entire area where the mesh was been 2 placed is blocked by this scarring.</p> <p>3 MR. THOMAS: Just show my objection to any 4 testimony to Bullets 2, 3 and 4 because it calls 5 for testimony about risks in the pelvic floor 6 which is beyond this witness's expertise.</p> <p>7 BY MR. ANDERSON:</p> <p>8 Q. Doctor, over the course of your 20 years of 9 research, how many explants from the abdominal wall 10 have you looked at and analyzed?</p> <p>11 A. We have meanwhile several thousand of 12 explanted meshes here that we have had a look to and 13 we try to analyze.</p> <p>14 Q. As part of this body of work over the last 20 15 years, how many explanted meshes from the pelvic 16 floor have you analyzed?</p> <p>17 A. It's up to 500.</p> <p>18 Q. Okay. So with regard to these thousands of 19 hernia mesh explants from humans that you have 20 analyzed and hundreds of pelvic floor explants that 21 you've analyzed over the course of these 20 years, 22 have you recognized similarities between the 23 contraction of the explanted abdominal wall meshes 24 and the explanted pelvic floor meshes?</p>	<p>1 polypropylene meshes that have been explanted? 2 A. We always found similar tissue response, and 3 we didn't find any significant difference in the 4 tissue reaction.</p> <p>5 Q. And with regard to the first two bullet 6 points on the slide that we were talking about a few 7 minutes ago, mesh inflammation is permanent and in 8 some patients mesh scarring is severe. Have you 9 arrived at those opinions based upon your 20 years of 10 work, all of your peer-reviewed publications, the 11 conferences you've spoken at around the world, the 12 conferences to urogynecologists and urologists at the 13 request of Ethicon, your review of thousands of 14 hernia mesh explants and your review of hundreds of 15 pelvic floor explants and over 50 that you have 16 reviewed yourself?</p> <p>17 MR. THOMAS: Objection.</p> <p>18 THE WITNESS: Yes, exactly.</p> <p>19 MR. THOMAS: Object to the form of question.</p> <p>20 THE WITNESS: It is.</p> <p>21 MR. ANDERSON: Whatever.</p> <p>22 BY MR. ANDERSON:</p> <p>23 Q. Go ahead.</p> <p>24 A. The permanence of the mesh inflammation, it's</p>
<p style="text-align: center;">Page 35</p> <p>1 MR. THOMAS: Show my objection to this to the 2 extent it's based upon his review of the 3 Klosterhalfen explants of the pelvic floor which 4 this court has already ruled is inappropriate for 5 him on which to rely for his opinions.</p> <p>6 MR. ANDERSON: Counsel, how about just saying 7 "objection"?</p> <p>8 MR. THOMAS: Because I didn't think it would 9 be clear from the record.</p> <p>10 BY MR. ANDERSON:</p> <p>11 Q. Have you personally reviewed pelvic floor 12 explants?</p> <p>13 A. Yes.</p> <p>14 Q. How many personal -- how many personal 15 reviews of pelvic floor explants have you done, 16 Dr. Klinige?</p> <p>17 MR. THOMAS: Same objection.</p> <p>18 THE WITNESS: It's about 50.</p> <p>19 BY MR. ANDERSON:</p> <p>20 Q. Okay. So of these 50 meshes that have been 21 taken out of women's bodies that you've analyzed and 22 the hundreds, if not thousands, that you've looked at 23 of hernia mesh explants, have you noticed 24 similarities in terms of the tissue response to the</p>	<p style="text-align: center;">Page 37</p> <p>1 a fact and that in some of these cases you have an 2 extended scarring. It is a fact. It is not related 3 to some specific location in the body.</p> <p>4 MR. ANDERSON: Okay. Let's show the next two 5 bullet points.</p> <p>6 BY MR. ANDERSON:</p> <p>7 Q. Doctor, based upon your review of all of the 8 Ethicon materials and the Ethicon depositions, your 9 review of the scientific literature in this case, 10 your 20 years of experience as a biomaterials 11 researcher, your experience as a hernia surgeon who's 12 treated -- not only implanted but treated 13 complications related to hernia, your review of 14 thousands of hernia mesh explants, your analysis 15 personally of 50 pelvic floor explants, and all of 16 the work that you've done to arrive at your opinions 17 in this case, can you state to a reasonable degree of 18 medical and scientific certainty as to whether or not 19 these two bullet points here are accurate?</p> <p>20 MR. THOMAS: Object to the form. Object; 21 goes beyond his expertise and beyond his 22 designation in the report.</p> <p>23 THE WITNESS: Yes. It is -- it is a fact 24 that if you have a chronic wound with a lot of</p>

Page 38	Page 40
<p>1 scar tissue, that, of course, you have a higher 2 risk for chronic pain, because of a higher risk 3 for getting nerves that are entrapped into the 4 scar tissue; and in the area of the pelvic floor 5 you have a higher risk of dyspareunia, erosions 6 and organ dysfunction. And, therefore, the 7 extent of inflammation and scarring is a very big 8 concern for the patient's safety. And if you 9 have a lot of inflammation, a lot of scar, this 10 carries a lot of risks for the patients.</p> <p>11 BY MR. ANDERSON:</p> <p>12 Q. Is there any way for a surgeon who is 13 implanting a Prolift mesh or a hernia mesh to know 14 the extent of scarring and contraction that will 15 occur over the patient's life in and around the mesh 16 or a way to control it?</p> <p>17 A. Not in regard to the specific response of a 18 patient, but for the general statement that the more 19 material, the more inflammation, then, of course, you 20 can estimate it.</p> <p>21 Q. Based upon your years of consulting with 22 Ethicon and all of your work over the last 20 years, 23 and your work with Ethicon, do you have personal 24 knowledge as to whether Ethicon was aware of these</p>	<p>1 Q. Are these documents significant to your 2 opinions -- strike that.</p> <p>3 Have you seen in the internal documents and 4 depositions of Ethicon witnesses discussions 5 regarding patient complications related to mesh 6 contraction?</p> <p>7 A. Yes.</p> <p>8 Q. Are these documents significant to your 9 opinions in this case?</p> <p>10 A. Yes.</p> <p>11 Q. Have you studied and published in the 12 peer-reviewed literature on the amount of shrinkage 13 or contraction that will occur in the human body to 14 polypropylene surgical meshes?</p> <p>15 A. Yes.</p> <p>16 Q. What have your studies shown regarding the 17 amount of shrinkage that occurs with polypropylene 18 meshes in the human body?</p> <p>19 A. Roughly you have to estimate a shrinkage, a 20 contraction of about 30 to 50 percent, but it depends 21 on the design of the mesh. So it can be much more; 22 it can be a little bit less.</p> <p>23 Q. How does the amount of foreign body material 24 in the mesh relate to the amount of mesh shrinkage or</p>
<p style="text-align: center;">Page 39</p> <p>1 issues with contraction and inflammation of their 2 polypropylene meshes that you have discussed?</p> <p>3 MR. THOMAS: Objection to what Ethicon knew.</p> <p>4 BY MR. ANDERSON:</p> <p>5 Q. Again, based upon your personal knowledge as 6 a consultant with Ethicon, did you have discussions 7 with them about the contraction of their 8 polypropylene meshes?</p> <p>9 A. Yes, I definitely know that we have discussed 10 this during our working group meetings with people 11 from Ethicon, exactly this problem of shrinkage, and 12 we have been trying to figure out what are the main 13 reasons. So, yeah, it was a finding from Ethicon as 14 well as from us --</p> <p>15 Q. And did you --</p> <p>16 A. -- working hand in hand.</p> <p>17 Q. I'm so sorry.</p> <p>18 And in this working hand in hand with Ethicon 19 in coming to these questions regarding mesh shrinkage 20 and its relationship to patient complications, did 21 you publish, while you were a consultant with 22 Ethicon, in the peer-reviewed literature on these 23 issues?</p> <p>24 A. Yes.</p>	<p style="text-align: center;">Page 41</p> <p>1 contraction that will occur in the tissue?</p> <p>2 A. The more material, the more inflammation, the 3 more scar, the more contraction, the more shrinkage.</p> <p>4 Q. Dr. Klinge, in the internal documents that 5 you have reviewed from Ethicon, have you seen 6 anywhere where they mention or address these concerns 7 over the amount of material with their Prolift mesh?</p> <p>8 A. Yes, I did.</p> <p>9 - - -</p> <p>10 (Plaintiff's Exhibit No. P0036, PowerPoint 11 presentation entitled "Stand & Deliver - Pelvic Floor 12 Repair", was marked for identification.)</p> <p>13 - - -</p> <p>14 BY MR. ANDERSON:</p> <p>15 Q. I'm showing you what has been marked as 16 Plaintiff's Exhibit P0036.</p> <p>17 Is this document something that you have 18 reviewed during your work in this litigation?</p> <p>19 A. Yes, I did.</p> <p>20 Q. Is it significant to your opinions in this 21 case?</p> <p>22 A. Yes.</p> <p>23 MR. THOMAS: What is the date of this 24 document?</p>

Page 42	Page 44
<p>1 MR. ANDERSON: It's in your production, and 2 so any Ethicon production, according to the 3 metadata, I believe it's 2008, but we can 4 certainly check that on a break.</p> <p>5 MR. THOMAS: Thank you. Just note my 6 objection to the use of any company documents 7 after the date of Mrs. Bellew's surgery.</p> <p>8 MR. ANDERSON: Oh, this is certainly before 9 Ms. Bellew's surgery.</p> <p>10 MR. THOMAS: I just wanted to make sure. 11 Thank you, Ben.</p> <p>12 BY MR. ANDERSON:</p> <p>13 Q. Is this document significant to your opinions 14 in this case?</p> <p>15 A. Yes.</p> <p>16 Q. Just explain briefly what this document is, 17 Dr. Klinke.</p> <p>18 A. It's a PowerPoint presentation from Ethicon.</p> <p>19 Q. Okay. If you go to page 7 of the document in 20 this Ethicon PowerPoint, you have seen this slide?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. Is this important to your opinions?</p> <p>23 A. Yes, it is important.</p> <p>24 Q. Can you explain why, please?</p>	<p>1 Initiation, August 25, 2008, was marked for 2 identification.) 3 - - -</p> <p>4 BY MR. ANDERSON:</p> <p>5 Q. Okay. I'm showing you what has been marked 6 as Plaintiff's Exhibit 1156.</p> <p>7 Are you familiar with this document, 8 Dr. Klinke?</p> <p>9 A. Yes, I am.</p> <p>10 Q. Is this something that you reviewed during 11 your work in this litigation?</p> <p>12 A. Yes, I did.</p> <p>13 Q. And is it significant to your opinions here 14 today?</p> <p>15 A. Yes, it is.</p> <p>16 Q. If we turn to page 12 of the document, is 17 this slide significant to your opinions?</p> <p>18 A. Yes.</p> <p>19 MR. ANDERSON: Can you blow up the right-hand 20 side of that?</p> <p>21 BY MR. ANDERSON:</p> <p>22 Q. Doctor, is this part of the PowerPoint slide 23 significant? And, if so, why?</p> <p>24 A. In this PowerPoint presentation from 2008</p>
<p>1 MR. ANDERSON: Blow up the -- yes.</p> <p>2 THE WITNESS: The topic of this slide is 3 "Improved Tissue Response," and so to get an 4 improved tissue response, the people that make 5 this presentation, they cited my work with 6 Klosterhalfen --</p> <p>7 MR. ANDERSON: If you could blow that up.</p> <p>8 THE WITNESS: -- where we wrote down the 9 entire concept of the lightweight and large pore 10 concept, and they figured out that for an 11 improved tissue response, you need a large porous 12 construction to reduce the tissue response. So 13 they are in line completely with what we have 14 found during these years, and they accepted it, 15 obviously.</p> <p>16 BY MR. ANDERSON:</p> <p>17 Q. And is this in line -- how does this relate 18 to your opinions regarding the amount of foreign body 19 reaction and the amount of inflammation?</p> <p>20 A. It's exactly in accordance. So, yeah.</p> <p>21 - - -</p> <p>22 (Plaintiff's Exhibit No. 1156, PowerPoint 23 presentation entitled "T-Pro (Thunder) - Pipeline 24 Leadership Team (PLT) - State Gate Discovery</p>	<p>1 from Ethicon, it is clearly stated that we need less 2 foreign body material. We need materials that 3 correlate to the physiological characteristics. So 4 it expresses that these people want to have less 5 material to make it safer.</p> <p>6 Q. Based upon your review of all of the 7 materials in this litigation and all the depositions 8 as well as your years of consulting with Ethicon, did 9 you determine whether or not they ever manufactured a 10 pelvic organ prolapse mesh with mesh that was 11 actually designed for the pelvic floor?</p> <p>12 A. No, I didn't -- didn't find any -- any 13 information to this.</p> <p>14 Q. The Gynemesh PS mesh and Prolift, was that 15 designed by Ethicon as a hernia mesh or a pelvic 16 floor mesh?</p> <p>17 A. To my knowledge, it was designed as a 18 material-reduced hernia mesh.</p> <p>19 Q. Okay. Dr. Klinke, I want to shift gears here 20 a little and talk to you about another mesh design 21 characteristic, and that is the pores. What are mesh 22 pores?</p> <p>23 A. A mesh is more or less a net, and the pore is 24 the area in between the filaments.</p>

Page 46	Page 48
<p>1 Q. Is the size of the pores or these open spaces 2 in the mesh material something that you have studied 3 over the last 20 years, published on in the 4 peer-reviewed literature, consulted with Ethicon 5 about and presented at conferences around the world 6 over the last 20 years?</p> <p>7 A. We did it extensively.</p> <p>8 Q. Is it also these open spaces or these pores a 9 design principle that you have used to work with 10 manufacturers to design safer meshes?</p> <p>11 A. Yes.</p> <p>12 Q. Can you tell us what the significance of 13 these pores or open spaces are with regard to the 14 tissue response for patients?</p> <p>15 A. The size of a pore means a critical parameter 16 to predict what happens when the tissue is -- or when 17 the mesh is incorporated into the tissue. If you 18 have very small pores, then the -- or the space in 19 between the fibers is completely filled by scar 20 tissue; and that makes the mesh stiff and rigid, 21 whereas if you have very large pores, large distances 22 between the fibers, the body is able to fill the 23 pores with fat tissue, and then the mesh remains 24 flexible, stretchable. So the small pores means a</p>	<p>1 the critical pore size or open space must be for a 2 surgical mesh implant for both hernia repair and 3 pelvic floor repair in order to be safe in the 4 tissues?</p> <p>5 A. Yes.</p> <p>6 Q. And what is that opinion?</p> <p>7 A. The larger the pores, the safer it is to -- 8 the larger the pores, the lower the risk for this 9 bridging; and for polypropylene, the critical figure 10 is about 1 millimeter.</p> <p>11 Q. And, again, we're on the metric system, but I 12 know the jury is going to see documents that some of 13 them are in millimeters and some are microns. What 14 does 1 millimeter equal in terms of microns?</p> <p>15 A. It equals 1,000 microns.</p> <p>16 Q. So 1 millimeter equals 1,000 microns?</p> <p>17 A. Yes.</p> <p>18 Q. So would -- I'm not real good at math, so 19 would 3 millimeters equal 3,000 microns?</p> <p>20 A. Exactly.</p> <p>21 Q. Okay. I got that one right.</p> <p>22 I know that you said you have over 1,000 23 publications in the peer-reviewed literature on the 24 safe design of surgical meshes. We obviously can't</p>
<p style="text-align: center;">Page 47</p> <p>1 considerable risk for the patient, whereas the larger 2 the pore, the less of the risk.</p> <p>3 Q. Is another way to say the larger the pore, 4 the greater the distance between the fibers of the 5 mesh?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. Have you conducted research over the 8 last 20 years, published peer-reviewed studies, and 9 worked as an Ethicon consultant on sufficient pore 10 size or how large these openings need to be in 11 surgical meshes to prevent these patient consequences 12 you are talking about?</p> <p>13 A. Yes, we did.</p> <p>14 Q. And has that research included analyzing the 15 pore size of meshes that are surgically removed from 16 animal models, abdominal wall, as well as the pelvic 17 floor?</p> <p>18 A. Yes.</p> <p>19 Q. And from your background, training, research, 20 your peer-reviewed publications, all your work for 21 the past 20 years. Your consulting work with 22 Ethicon, all the materials that you have reviewed in 23 this case, do you have an opinion to a reasonable 24 degree of medical and scientific certainty as to what</p>	<p style="text-align: center;">Page 49</p> <p>1 go through all of those today, but I did want to show 2 the jury just a couple of your peer-reviewed 3 publications contained in your research on the 4 relationship between inflammation and contraction and 5 adequate mesh pore size for polypropylene meshes. 6 Okay?</p> <p>7 A. Yes.</p> <p>8 ---</p> <p>9 (Plaintiff's Exhibit No. PLT0260, Article 10 entitled "Impact of Polymer Pore Size on the 11 Interface Scar Formation in a Rat Model", was marked 12 for identification.)</p> <p>13 ---</p> <p>14 BY MR. ANDERSON:</p> <p>15 Q. I'm showing you what we have marked as 16 Plaintiff's Exhibit PLT0260.</p> <p>17 MR. ANDERSON: Counsel.</p> <p>18 If you'll highlight the top.</p> <p>19 BY MR. ANDERSON:</p> <p>20 Q. Is this one of your peer-reviewed 21 publications on polymer pore size?</p> <p>22 A. Yes, it is.</p> <p>23 MR. ANDERSON: And if we could turn to 24 page 213 and enlarge the left side of the</p>

Page 50	Page 52
<p>1 document down there where it says "loose 2 network."</p> <p>3 BY MR. ANDERSON:</p> <p>4 Q. Doctor, drawing your attention to this part 5 of your peer-reviewed publication from 2002, what 6 does that statement tell us in terms of this 7 relationship between these -- the distance between 8 the fibers and patient complications?</p> <p>9 A. In this publication from 2002, we described 10 that we found that if you have larger pores of more 11 than 1, 2 millimeters, then the scar tissue is 12 limited to the fibers and that the pores, the holes 13 in between the fibers, are filled by fat tissue. So 14 these are the good pores, whereas if you have smaller 15 pores, less than 1 millimeter, you usually have scar 16 tissue linking these fibers strongly to each other 17 and making the entire implant stiff and rigid.</p> <p>18 Q. And just to be clear, Doctor, does that mean 19 that every pore from an explanted mesh that is less 20 than 1,000 microns, that every one of them is going 21 to be filled with scar?</p> <p>22 A. No. But the risk is very, very high that 23 these pores are filled by scar tissue; and, 24 therefore, you have to say, the larger the pore, the</p>	<p>1 Q. And in this 2005 article, does it discuss 2 your research on inflammation and scarring and its 3 relationship to adequate pore size?</p> <p>4 A. Yes.</p> <p>5 MR. ANDERSON: If we go to the second page of 6 the article and we blow up this left side, if you 7 could draw up some language there and do the 8 photograph underneath it as well. Thank you, 9 Michael.</p> <p>10 BY MR. ANDERSON:</p> <p>11 Q. Explain to the jury if this has any 12 significance to you in this relationship of pore size 13 of a mesh and patient complications.</p> <p>14 A. So this manuscript basically is a summary of 15 these ten-year works.</p> <p>16 Q. Ten-year work with Ethicon you mean?</p> <p>17 A. With Ethicon where we wanted to develop safer 18 meshes together with them. And you see an example of 19 small pore meshes on the left side with the number 20 "A" there. These are very small pores, and these are 21 all filled up by scar tissue, making this rigid mesh 22 scar compound.</p> <p>23 Q. Well, it's not filled with scar tissue in 24 this picture.</p>
<p style="text-align: center;">Page 51</p> <p>1 lesser the risk.</p> <p>2 Q. So the higher the -- the further the distance 3 of the fibers above 1,000 microns, the less risk of 4 this bridging of the scar tissue?</p> <p>5 A. Yeah, less risk and make it more safer, then, 6 for the patient.</p> <p>7 Q. Okay. And if we could just turn to the last 8 page.</p> <p>9 Who funded this study that you did regarding 10 impact of polymer pore science?</p> <p>11 A. These findings were part and as a result of 12 our collaboration in these ten years where we worked 13 together with the people from Ethicon.</p> <p>14 - - -</p> <p>15 (Plaintiff's Exhibit No. PLT0271, Article 16 entitled "The lightweight and large porous concept 17 for hernia repair", was marked for identification.)</p> <p>18 - - -</p> <p>19 BY MR. ANDERSON:</p> <p>20 Q. I'm now handing you what has been marked as 21 Plaintiff's PLT0271.</p> <p>22 Do you recognize this as another one of your 23 peer-reviewed publications?</p> <p>24 A. Yes.</p>	<p style="text-align: center;">Page 53</p> <p>1 A. No. These -- these are images from the 2 textile that you're taking out of the box; but if you 3 are placing these meshes into the tissues, then you 4 will find as a result this integration into thick 5 scar tissue, making this small pore net a high risk 6 device for -- with a high risk for getting 7 complications.</p> <p>8 On the right side you see what is possible, 9 and that is the development that we, together with 10 Ethicon, realized, that we enlarged -- we make the 11 pores much larger, up to 3 to 5 millimeters. And if 12 you place this textile construction into the tissues 13 and then look afterwards what happens, you will find 14 a very flexible, thin mesh tissue compound which is 15 integrated into fat tissue. And, therefore, it is a 16 good example that by reduction of the material to 30 17 percent of this of the left side by making the pores 18 larger, that you can improve significantly the 19 reaction of their surrounding tissue.</p> <p>20 Q. So when you were talking about wanting to 21 have this good tissue, this fat tissue in the pores 22 or the open spaces, in the figure to the right in B, 23 would that be the area where it's the open diamond 24 space?</p>

Page 54	Page 56
<p>1 A. Yes.</p> <p>2 Q. That's the area you want the fat tissue to</p> <p>3 grow?</p> <p>4 A. There we want to have this fat tissue,</p> <p>5 because this fat tissue keeps it flexible,</p> <p>6 stretchable, elastic.</p> <p>7 - - -</p> <p>8 (Plaintiff's Exhibit No. P1679, PowerPoint</p> <p>9 presentation entitled "Factors related to mesh</p> <p>10 shrinkage - What do we know? A review of literature</p> <p>11 and internal studies", was marked for</p> <p>12 identification.)</p> <p>13 - - -</p> <p>14 BY MR. ANDERSON:</p> <p>15 Q. Okay. I'm going to show you a document,</p> <p>16 Plaintiff's Exhibit P1679.</p> <p>17 Have you seen this document before, Doctor?</p> <p>18 A. Yes, I've seen it.</p> <p>19 Q. And is it something that you saw in this</p> <p>20 litigation and it is significant to your opinions in</p> <p>21 this case?</p> <p>22 A. Yes, it is.</p> <p>23 Q. Okay. And what is this document, if you</p> <p>24 would?</p>	<p>1 A. Bridging means that the scar is filling out</p> <p>2 completely the pores, the room in between the fibers,</p> <p>3 which means a risk.</p> <p>4 Q. A risk -- what type of risk, Doctor?</p> <p>5 A. A risk for contraction of the scar and the</p> <p>6 mesh and pain and erosion and dysfunction.</p> <p>7 Q. As the pore sizes of a mesh in use are</p> <p>8 greater than 1 millimeter or 1,000 microns, in your</p> <p>9 opinion will that reduce the risk of contraction?</p> <p>10 A. Yes.</p> <p>11 Q. And with pore sizes in use that are less than</p> <p>12 1,000 microns, or 1 millimeter, in your opinion will</p> <p>13 that increase the risk of mesh shrinkage or</p> <p>14 contraction?</p> <p>15 A. Definitely, yes.</p> <p>16 MR. THOMAS: Just show my objection to</p> <p>17 leading questions.</p> <p>18 BY MR. ANDERSON:</p> <p>19 Q. Go ahead.</p> <p>20 A. So definitely. A pore size below</p> <p>21 1 millimeter will increase the risk for scar bridging</p> <p>22 and will increase the risk for complications.</p> <p>23 Q. Dr. Klinge, I now want to talk about another</p> <p>24 concept with you, and that's about how and when it is</p>
<p>1 A. It's an Ethicon document showing or dealing</p> <p>2 with the factors related to mesh shrinkage.</p> <p>3 Q. If we could just turn over, please, to</p> <p>4 page 12 of this PowerPoint. And what is the date on</p> <p>5 the bottom left there?</p> <p>6 MR. ANDERSON: If you could blow that up.</p> <p>7 BY MR. ANDERSON:</p> <p>8 Q. What is the date of this PowerPoint, Doctor?</p> <p>9 A. It is done in 2007.</p> <p>10 MR. ANDERSON: Okay. Take down the blowup.</p> <p>11 BY MR. ANDERSON:</p> <p>12 Q. And what do we find from this particular</p> <p>13 slide?</p> <p>14 MR. ANDERSON: And if you would highlight the</p> <p>15 bullet point 2 from this Ethicon PowerPoint.</p> <p>16 THE WITNESS: The people who made this, they</p> <p>17 acknowledge that the pore size has to be more</p> <p>18 than 1 millimeter to avoid this fibrotic bridging</p> <p>19 or this dangerous scarring of the holes.</p> <p>20 BY MR. ANDERSON:</p> <p>21 Q. Okay. So fibrotic bridging, fibrosis relates</p> <p>22 to what?</p> <p>23 A. Scar.</p> <p>24 Q. And bridging relates to what?</p>	<p>1 important to measure the pores of meshes like</p> <p>2 Prolift. I know that you asked me to bring a</p> <p>3 basketball net here today to help provide at least a</p> <p>4 simple explanation to begin with of the importance of</p> <p>5 the pore measurements; is that correct?</p> <p>6 A. Yes.</p> <p>7 MR. ANDERSON: Okay. Just for demonstrative</p> <p>8 purposes and for the record, we have marked the</p> <p>9 basketball net as Plaintiff's Exhibit P3365.</p> <p>10 - - -</p> <p>11 (Plaintiff's Exhibit No. P3365, Basketball</p> <p>12 net, was marked for identification.)</p> <p>13 - - -</p> <p>14 MR. ANDERSON: Are you ready? Okay. Thank</p> <p>15 you.</p> <p>16 BY MR. ANDERSON:</p> <p>17 Q. So, Doctor, explain what you're trying to</p> <p>18 show the jury here with regard to pore size and pore</p> <p>19 measurement.</p> <p>20 A. So we know that the pore size is critical for</p> <p>21 the tissue reaction. We want to have large pores.</p> <p>22 When you are taking out a net of the box, then the</p> <p>23 pores may be sufficient; but if you have it in use,</p> <p>24 if you implanted it and if the surgeon puts some even</p>

Page 58	Page 60
<p>1 slight forces to it, you see that you have this 2 collapse of pores, that even very small pores can get 3 very, very small. And, therefore, by applying these 4 forces to a net, it can make a large pore net to a 5 small pore net and, thereby, increases the risks 6 considerably.</p> <p>7 Q. So in your opinion, in terms of patient 8 safety, when is it important to look at the greatest 9 distance between the fibers? Before it goes in the 10 body or after?</p> <p>11 MR. THOMAS: Objection.</p> <p>12 Q. Or after it's used?</p> <p>13 MR. THOMAS: Objection; foundation, expertise 14 designation.</p> <p>15 BY MR. ANDERSON:</p> <p>16 Q. Go ahead, Doctor.</p> <p>17 A. You have to take into account that any force 18 can lead to a pore collapse, and if you want to use a 19 mesh in an area where these forces may occur, then, 20 of course, you have to analyze the pore size in use.</p> <p>21 Q. Doctor, did you do testing on the Prolift 22 mesh to determine what would happen to the Prolift 23 pores when stretch forces are applied, for instance, 24 when the Prolift is going to be implanted in a woman?</p>	<p>1 machine, the details of it in 2007, and later on some 2 of the results in 2013.</p> <p>3 Q. And do those peer-reviewed publications cover 4 all of the protocols and the test methods and the 5 setup and analysis of the testing?</p> <p>6 A. Yes. In every detail.</p> <p>7 Q. And did one of those publications actually 8 involve testing of the Prolift device on this machine 9 in order to investigate the pores after stretch is 10 applied?</p> <p>11 A. Yes, it is.</p> <p>12 Q. And were you involved in the development of 13 the testing and the protocols and parameters for the 14 pore testing for that 2013 article looking at the 15 Prolift mesh?</p> <p>16 A. Yes, I was involved in all of this, and I was 17 the medical doctor who was responsible for the 18 interpretation and analysis of this data.</p> <p>19 Q. Did the testing that was published by you in 20 2013 include testing on the Prolift arms?</p> <p>21 A. Yes, it did.</p> <p>22 - - -</p> <p>23 (Plaintiff's Exhibit No. PLT0697, Article 24 entitled "Elongation of textile pelvic floor implants</p>
Page 59	Page 61
<p>1 Did you do testing?</p> <p>2 A. We did it.</p> <p>3 Q. Please explain just generally the testing 4 that you were involved in regarding looking at the 5 pores after forces are applied to them.</p> <p>6 A. In 2005 I met with a colleague of mine from 7 the technical university, Prof. Dr. Thomas Mühl, and 8 we wanted to develop a machine that makes it possible 9 to really measure pore sizes and to really give a 10 measurement what happens to the pores when applying 11 some forces to it. We want to have a measurement 12 that is reproducible, that is objective, and that is 13 reliable. And this has not been done before and, 14 therefore, we developed this machine and finally 15 could finish our work in 2007.</p> <p>16 Q. Was that work published in the peer-reviewed 17 literature?</p> <p>18 A. Yes. We publish everything and didn't want 19 to restrict it because we -- we want to make it 20 public so that everyone can use this way to optimize 21 his research and development.</p> <p>22 Q. And when was that information published in 23 the peer-reviewed literature?</p> <p>24 A. We published this, the technique, the</p>	<p>1 under load is related to complete loss of effective 2 porosity, thereby favoring incorporation in scar 3 plates", was marked for identification.)</p> <p>4 - - -</p> <p>5 BY MR. ANDERSON:</p> <p>6 Q. I'm showing you what has been marked as 7 Plaintiff's Exhibit PLT0697. Doctor, is this that 8 2013 publication regarding your testing of the 9 Prolift device?</p> <p>10 A. Yes, it is.</p> <p>11 MR. ANDERSON: If you would hit that. Yeah.</p> <p>12 BY MR. ANDERSON:</p> <p>13 Q. And if you could please go with me to page 5. 14 And we have blown up the left-hand side and have some 15 images as well as the figure box below that.</p> <p>16 What are we seeing here, Doctor, in terms of 17 the testing in this scientific research that you did?</p> <p>18 A. In the upper part you are just seeing an 19 image of the Gynemesh PS or the Prolift mesh without 20 applying any tension to it. You see the black lines. 21 These are the fibers, and the room in between these 22 are the pores.</p> <p>23 Q. And, Doctor, how much force was applied to 24 the Prolift arms that we're seeing in this testing</p>

Page 62	Page 64
<p>1 that was published in 2013?</p> <p>2 A. So, yeah, I forgot to explain. The lower</p> <p>3 image shows the same structure when applying some</p> <p>4 force to it. So you see the same change as you see</p> <p>5 with the basketball net. When you apply some forces</p> <p>6 to it, you find -- you see a collapse of the pores.</p> <p>7 The pores -- the force that we applied in this</p> <p>8 experiment was 4.9 newton. That is around one pound.</p> <p>9 Q. How did you determine what forces you were</p> <p>10 going to place on the Prolift arms during this</p> <p>11 testing that's published in 2013?</p> <p>12 A. We had been looking to the many Ethicon</p> <p>13 internal documents, and we wanted to keep below their</p> <p>14 limits what they assume to be reasonable limits, and</p> <p>15 we found two references, at least two references.</p> <p>16 Q. And when you're saying references, are you</p> <p>17 talking about references in the Ethicon documents to</p> <p>18 the foreseeable amounts of forces that would be</p> <p>19 placed on the arms during the implantation of the</p> <p>20 Prolift?</p> <p>21 A. Yes.</p> <p>22 - - -</p> <p>23 (Plaintiff's Demonstrative Exhibit No. P3360,</p> <p>24 PowerPoint slide, a blowup referencing PLT0697,</p>	<p>1 Applicability/Suitability, Bates stamped</p> <p>2 ETH.MESH.01992234 through ETH.MESH.01992237, was</p> <p>3 marked for identification.)</p> <p>4 - - -</p> <p>5 BY MR. ANDERSON:</p> <p>6 Q. I'm showing you, Doctor, what the plaintiffs</p> <p>7 have marked and is noted on the slide as Plaintiff's</p> <p>8 0777, is this the document where they estimated</p> <p>9 approximately 5 pounds of force?</p> <p>10 A. Yes, it is.</p> <p>11 Q. And does 2.3 newtons per centimeter estimate</p> <p>12 to about 5 pounds of force?</p> <p>13 A. Yes.</p> <p>14 - - -</p> <p>15 (Plaintiff's Demonstrative Exhibit No. P3357,</p> <p>16 Document Bates stamped ETH-01755, was marked for</p> <p>17 identification.)</p> <p>18 - - -</p> <p>19 BY MR. ANDERSON:</p> <p>20 Q. Okay. And then showing you what has been</p> <p>21 marked as Plaintiff's Exhibit P3357, is this the</p> <p>22 document that you referenced in terms of Ethicon</p> <p>23 stating that you could estimate 12 pounds of force by</p> <p>24 the surgeon being placed on the Prolift arms during a</p>
<p style="text-align: center;">Page 63</p> <p>1 "Elongation of textile pelvic floor implants under</p> <p>2 load is related to complete loss of effective</p> <p>3 porosity, thereby favoring incorporation in scar</p> <p>4 plates", was marked for identification.)</p> <p>5 - - -</p> <p>6 BY MR. ANDERSON:</p> <p>7 Q. Okay. And we created a slide, I think, to</p> <p>8 help the jury with that demonstrative, Plaintiff's</p> <p>9 Exhibit 3360.</p> <p>10 MR. ANDERSON: If you could just put in those</p> <p>11 two references.</p> <p>12 BY MR. ANDERSON:</p> <p>13 Q. And, Doctor, are these the two references</p> <p>14 from the Ethicon documents regarding two different</p> <p>15 estimated forces that may be placed on the arms?</p> <p>16 A. Yes. In these two documents you find either</p> <p>17 5 pounds in the one document or even 12 pounds in the</p> <p>18 other, and so we wanted to be below this range, not</p> <p>19 to show that there is a collapse with extremely high</p> <p>20 forces, but we want to know what happens to pores</p> <p>21 when applying just 1 pound.</p> <p>22 - - -</p> <p>23 (Plaintiff's Exhibit No. P0777, Ethicon</p> <p>24 document, Form for Test Method</p>	<p style="text-align: center;">Page 65</p> <p>1 Prolift procedure?</p> <p>2 A. Exactly.</p> <p>3 Q. Okay. Thank you.</p> <p>4 Doctor, what is the significance of your</p> <p>5 findings with regard to the mesh that we see that has</p> <p>6 had 1.1 pounds of force applied to it in terms of the</p> <p>7 tissue response in the patient?</p> <p>8 A. It clearly demonstrates and confirms that you</p> <p>9 have a change of the pore size when applying some</p> <p>10 force to it and that even very low forces can lead to</p> <p>11 very, very small pore mesh -- meshes; and, therefore,</p> <p>12 the application of slight forces changing the</p> <p>13 appearance of a mesh like this will increase risks.</p> <p>14 Q. Okay. Well, put it simply, what does that</p> <p>15 mesh on the bottom mean to the patient?</p> <p>16 MR. THOMAS: Objection; foundation,</p> <p>17 expertise.</p> <p>18 BY MR. ANDERSON:</p> <p>19 Q. Yeah. I think we've laid your foundation for</p> <p>20 expertise. Go ahead, Doctor.</p> <p>21 A. The mesh will mean increased risk for scar</p> <p>22 bridging, shrinkage, contraction, pain, erosion.</p> <p>23 Q. Okay. In your review of the internal Ethicon</p> <p>24 documents in this case, did you determine whether</p>

Page 66	Page 68
<p>1 Ethicon's scientists had considered your and 2 Dr. Mühl's pore testing publications and the effects 3 of mesh pore size under strain? 4 A. Yes, I did. 5 - - - 6 (Plaintiff's Exhibit No. P0829, E-mail chain 7 and article entitled "New Objective Measurement to 8 Characterize the Porosity of Textile Implants," Bates 9 stamped ETH.MESH.02184130 through ETH.MESH.02184138, 10 was marked for identification.) 11 - - - 12 BY MR. ANDERSON: 13 Q. Let's pull up the two documents so the jury 14 can see what we're talking about. 15 I'm handing you what has been premarked as 16 Plaintiff's Exhibit P0829. Have you seen this 17 document before, Dr. Klinge? 18 A. Yes, I've seen. 19 Q. Is this something you considered and reviewed 20 in arriving at your opinions in this case? 21 A. Yes. 22 MR. ANDERSON: If we could blow up the top 23 part of this and also show the attachment that 24 goes with this article -- with this internal</p>	<p>1 Hamburg, Ethicon. 2 Q. Did you work with him in the last 20 years? 3 A. He was a member of the working group that has 4 been working together with us. 5 Q. And if we see the attachment to this e-mail, 6 two years later what do you find here, Doctor? 7 MR. THOMAS: Objection; postdates 8 Ms. Bellew's surgery, and there is nothing here 9 to comment on other than the fact it's just a 10 transmittal letter. 11 BY MR. ANDERSON: 12 Q. Go ahead, Doctor. 13 A. In 2010 they again circulated it to the 14 members of their research groups. 15 - - - 16 (Plaintiff's Exhibit No. P1087, PowerPoint 17 presentation entitled "Thunder: Technical Review, 18 Somerville 28th February 2008", was marked for 19 identification.) 20 - - - 21 BY MR. ANDERSON: 22 Q. I'm showing you what has been marked as 23 Plaintiff's Exhibit P1087. 24 Have you seen this document before,</p>
Page 67	Page 69
<p>1 Ethicon e-mail. Yes. 2 BY MR. ANDERSON: 3 Q. Explain what the significance is to you of 4 this e-mail in 2008 as well as the attachment. 5 MR. THOMAS: Objection; calls for Ethicon's 6 state of mind. 7 THE WITNESS: They are circulating our 8 manuscript that we published in 2005 as a 9 sophisticated method to measure porosity, so they 10 have been aware of it. 11 - - - 12 (Plaintiff's Exhibit No. P1437, October 7, 13 2010, e-mail and article entitled "New Objective 14 Measurement to Characterize the Porosity of Textile 15 Implants," Bates stamped ETH.MESH.04945136 through 16 ETH.MESH.04945144, was marked for identification.) 17 - - - 18 BY MR. ANDERSON: 19 Q. Okay. Let me show you another document which 20 is Plaintiff's Exhibit 1437, which is another e-mail, 21 an Ethicon e-mail, this one dated 2010, from a 22 Dr. Joerg Holste to a Dr. Juergen Trzewik. Do you 23 know Dr. Joerg Holste? 24 A. Yes, I know. He is a leading scientist in</p>	<p>1 Dr. Klinge? 2 A. Yes, I've seen it. 3 Q. And is it significant to your opinions in 4 this case today? 5 A. Yes, it is. 6 Q. And what generally is this document? 7 A. It's a technical review from Ethicon. 8 Q. And what year is this dated? 9 A. It's made from 2008. 10 Q. If you would turn, please, over to page 21 of 11 Plaintiff's Exhibit 1087. Is this slide of the 12 PowerPoint something you've seen before? 13 A. Yes, I've seen it. 14 Q. And is this significant to your opinions with 15 regard to a pore collapse and pore deformation and 16 its relation to patient injury? 17 A. Yeah. 18 Q. Okay. What do you see here, Doctor, that you 19 would like to point out to the jury? 20 MR. ANDERSON: Highlight 4. 21 A. So in this definition of the requirements to 22 improve, as it is said in the subtitle, "Improving 23 lives by advancing the standard of care in tissue 24 repair," they identify it as an important point to</p>

Page 70	Page 72
<p>1 improve this -- these results, shrinkage and 2 stiffening; and they defined a pore size of more than 3 3 millimeter as being essential, and for the first 4 time they mentioned a pore size of 1 millimeter under 5 stretch. So they acknowledged that you have to look 6 to the pore size and use additionally to the pore 7 size in the box or without any forces.</p> <p>8 MR. THOMAS: Objection; move to strike. Goes 9 beyond what the document says.</p> <p>10 BY MR. ANDERSON:</p> <p>11 Q. I want to go back to a document previously 12 used, which was Plaintiff's Exhibit 1156. We looked 13 at this with the jury a little earlier today, and --</p> <p>14 MR. THOMAS: Can you give me just a second, 15 please?</p> <p>16 MR. ANDERSON: Sure.</p> <p>17 MR. THOMAS: Thank you. I have it now.</p> <p>18 BY MR. ANDERSON:</p> <p>19 Q. Okay. If you go to page 13 of this 2008 20 Ethicon PowerPoint, have you seen this slide before, 21 Doctor?</p> <p>22 A. Yes, I've seen it.</p> <p>23 Q. And is that significant to your opinions in 24 this case?</p>	<p>1 the force to it.</p> <p>2 Q. Thank you, Doctor.</p> <p>3 - - -</p> <p>4 (Plaintiff's Exhibit No. P2995, PowerPoint 5 presentation entitled "Mesh Properties - How 6 important are they?" was marked for identification.)</p> <p>7 - - -</p> <p>8 BY MR. ANDERSON:</p> <p>9 Q. Going -- I want to show you now Plaintiff's 10 Exhibit P2995. Is this a document that you have 11 reviewed and relied upon in this litigation?</p> <p>12 A. Yes, I did.</p> <p>13 Q. And what is this, Doctor?</p> <p>14 A. This is a PowerPoint presentation from 15 Ethicon.</p> <p>16 Q. And if we would go to slide 25 of this 17 presentation by Ethicon.</p> <p>18 A. Yes.</p> <p>19 Q. Is that significant to your opinions that 20 you're offering here regarding pore size and pore 21 deformation after stretch is applied?</p> <p>22 A. Yes, it is.</p> <p>23 Q. Okay. Please explain for the jury.</p> <p>24 A. Because this figure wants to express in the</p>
Page 71	Page 73
<p>1 A. Yes.</p> <p>2 MR. ANDERSON: Okay. Highlight the left-hand 3 side of this picture.</p> <p>4 BY MR. ANDERSON:</p> <p>5 Q. What are we seeing here, Doctor?</p> <p>6 A. So in this image you see the same phenomenon 7 as we have seen in -- with the basketball net, that 8 when applying some forces, the pores collapse and you 9 will create a small pore mesh.</p> <p>10 Q. We see the word "effective porosity" there. 11 What's that refer to?</p> <p>12 A. Effective porosity, that's exactly the term 13 that we were able to define with the testing that we 14 do a lot of, Professor Mühl. So they adopted this 15 terminology in --</p> <p>16 Q. Just explain that real simply for the jury, 17 what effective pores would be.</p> <p>18 A. So effective pores means that is the area of 19 the good pores roughly. So the good pores are those 20 with fat. If you start with half of the pores are 21 filled by fat in the upper line, then it's going to 22 zero in the lower if you applied some force to it. 23 So you only have small pores, non-effective, poor 24 pores, risky pores in the lower part when you apply</p>	<p>1 title already that large pores become very small 2 under stress, and it was in contrast to the previous 3 one, which was a drawing. It shows that was an 4 Ethicon experiment showing or trying to demonstrate 5 what happens to the textile structure to the pores 6 when applying a force to it.</p> <p>7 Q. As part of your review of the materials in 8 this case, did you see the Ethicon video of a Prolift 9 anterior actually being implanted in a woman?</p> <p>10 A. Yes, I did.</p> <p>11 Q. And is that video significant to your 12 opinions in this case?</p> <p>13 A. Yes, it is.</p> <p>14 Q. Okay. I don't want to have to show the jury 15 the entire video because they may have already seen 16 it, but did you ask me to create some screenshots 17 from that video?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. And did we create a slide showing 20 these videos --</p> <p>21 A. Yes.</p> <p>22 Q. -- these screenshots for the jury?</p> <p>23 A. Sorry.</p> <p>24 Q. Sorry. Yes?</p>

Page 74	Page 76
<p>1 A. Yes.</p> <p>2 ---</p> <p>3 (Plaintiff's Demonstrative Exhibit No. P3361,</p> <p>4 PowerPoint slide entitled "Pores Collapse Under</p> <p>5 Tension," referencing P2995, ETH.MESH.05237872, PLT</p> <p>6 0697, P1452 - ETH.MESH.000007, was marked for</p> <p>7 identification.)</p> <p>8 ---</p> <p>9 BY MR. ANDERSON:</p> <p>10 Q. Okay. I'll put up this next slide which</p> <p>11 we'll use for demonstrative as P3361. Just one</p> <p>12 second. Go ahead.</p> <p>13 MR. THOMAS: Before you show that to the</p> <p>14 jury, are you representing that this is</p> <p>15 Ms. Bellew's surgery?</p> <p>16 MR. ANDERSON: If I did, I would have said</p> <p>17 that.</p> <p>18 MR. THOMAS: That's why I show my objection</p> <p>19 to this not being representative of Ms. Bellew's</p> <p>20 surgery.</p> <p>21 MR. ANDERSON: It's okay. It's your</p> <p>22 document.</p> <p>23 BY MR. ANDERSON:</p> <p>24 Q. So showing you Plaintiff's Exhibit P3361,</p>	<p>1 A. Obviously the forces in the OR when in use</p> <p>2 are too high for this specific design of this mesh,</p> <p>3 leading to this roping, even in this teaching video.</p> <p>4 MR. THOMAS: Objection; move to strike,</p> <p>5 beyond the area of expertise and not a disclosed</p> <p>6 opinion.</p> <p>7 MR. ANDERSON: It certainly was disclosed</p> <p>8 opinions, and the videos are in his reliance</p> <p>9 materials. And he talked about initial force, 12</p> <p>10 pounds of force. He talks about 5 pounds of</p> <p>11 force. He says that when you use the applied</p> <p>12 loads that Ethicon used that you get to see pore</p> <p>13 deformation. He said that you see it from</p> <p>14 Ethicon's documents, his documents and the DVD.</p> <p>15 BY MR. ANDERSON:</p> <p>16 Q. Okay. So if we can just zoom in on this</p> <p>17 Ethicon DVD on the right-hand side produced by</p> <p>18 Ethicon in this litigation, is that significant to</p> <p>19 your opinions? Is that what you were discussing with</p> <p>20 the jury of how the mesh is curled and roped and</p> <p>21 deformed?</p> <p>22 A. Yes.</p> <p>23 MR. THOMAS: Same objection.</p> <p>24 THE WITNESS: Exactly. So this is not longer</p>
<p style="text-align: center;">Page 75</p> <p>1 over to the right is that a screen shot from a DVD</p> <p>2 produced by Ethicon of Ethicon surgeons implanting a</p> <p>3 Prolift anterior into a woman?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. So you asked me to put these three</p> <p>6 images together. Why did you ask me to do that? Why</p> <p>7 do you think that's important for the jury to see,</p> <p>8 Doctor?</p> <p>9 A. Because it makes very clear that we have to</p> <p>10 deal with a realistic problem. On the left you see</p> <p>11 the image from the Ethicon study where they just</p> <p>12 described it.</p> <p>13 In the middle you see an image of our testing</p> <p>14 where we tried to measure it to quantify the</p> <p>15 consequences to different forces.</p> <p>16 And on the right you see exactly the same</p> <p>17 deformation, the same roping of the arms during the</p> <p>18 OR. So the collapse of pores is a real phenomenon.</p> <p>19 Q. So whether we can take the Ethicon document</p> <p>20 that says 5 pounds of force is placed by the surgeon</p> <p>21 on the arms during implant or 12 pounds of force</p> <p>22 during implant, this image to the right, is this the</p> <p>23 resulting characterization of the mesh arm after</p> <p>24 either 5 or 12 pounds of force are placed on it?</p>	<p style="text-align: center;">Page 77</p> <p>1 any large pore mesh design. This rope will be</p> <p>2 integrated into dense scar tissue and nothing --</p> <p>3 nothing else, and it will become stiff and rigid.</p> <p>4 BY MR. ANDERSON:</p> <p>5 Q. Is that appearance of the arm right there, is</p> <p>6 that what it looks like when it comes out of the</p> <p>7 Ethicon box?</p> <p>8 A. No, definitely not.</p> <p>9 MR. ANDERSON: Okay. You can take that down.</p> <p>10 Oh, actually, bring that back up.</p> <p>11 BY MR. ANDERSON:</p> <p>12 Q. Do you have an opinion to a reasonable degree</p> <p>13 of medical and scientific certainty as to whether the</p> <p>14 mesh arms that the jury is seeing in the right-hand</p> <p>15 picture would result in unnecessary risk to the</p> <p>16 tissues?</p> <p>17 MR. THOMAS: Objection; beyond his area of</p> <p>18 expertise.</p> <p>19 THE WITNESS: The appearance of such a mesh</p> <p>20 in this roping form means a considerable risk,</p> <p>21 and because it is -- there is no need for this,</p> <p>22 it is an unnecessary risk.</p> <p>23 BY MR. ANDERSON:</p> <p>24 Q. And would that unnecessary risk involving the</p>

Page 78	Page 80
<p>1 tissue response, would that risk be the same with 2 mesh of this appearance whether it was in the 3 abdominal tissue, the pelvic tissue or the tissue 4 under your armpit?</p> <p>5 MR. THOMAS: Same objection.</p> <p>6 THE WITNESS: A mesh curled like this, 7 getting these small pores like this one will 8 result everywhere in the body in a scar mesh 9 compound that is stiff and rigid and not flexible 10 any longer.</p> <p>11 MR. ANDERSON: You can take that down.</p> <p>12 BY MR. ANDERSON:</p> <p>13 Q. After your review of all the materials in 14 this case regarding Ethicon's meshes for treating 15 pelvic organ prolapse, all of your work that you've 16 done in the scientific literature, conferences you've 17 spoken at around the world, the conferences you've 18 spoken as an invited lecture by Ethicon, and your 19 work as a hernia surgeon both implanting and 20 explanting polypropylene meshes, your work in 21 reviewing thousands of hernia mesh explants from 22 humans, your review of looking at explants from 23 pelvic floor -- from the pelvic floor in women, do 24 you have an opinion to a reasonable degree of medical</p>	<p>1 BY MR. ANDERSON:</p> <p>2 Q. Is this the PowerPoint that you wanted me to 3 prepare, Doctor?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. You have a point there, "Less 6 Material = Safer," under the heading "Prolift 7 Unsafe/Defective Mesh Design." What do you mean by 8 this first bullet point?</p> <p>9 A. It became clear from all our work that less 10 material would reduce the risk of inflammation and 11 scarring, so less material will make it safer and 12 there is no need for this amount of material as it is 13 used for the Prolift.</p> <p>14 Q. Okay. Let's go to your next point.</p> <p>15 A. From all our work, it is evident and clear 16 and undoubted that large pore -- larger pores will 17 make it safer. They will help that the pores are 18 filled by fat tissue, keeping it flexible. So, 19 therefore, larger pores would make it safer, and 20 there is no need for the small pores of the Prolift.</p> <p>21 Q. And your third point?</p> <p>22 A. The pores have to resist a collapse when 23 applied, some forces that we have seen that these 24 forces have been applied. And, therefore, a mesh</p>
<p>1 and scientific certainty as to whether the Prolift 2 was a safe design or an unsafe defective design?</p> <p>3 MR. THOMAS: Objection.</p> <p>4 A. I have --</p> <p>5 MR. THOMAS: Excuse me. Just let me base my 6 objection to the foundation that he's laid. Go 7 ahead.</p> <p>8 BY MR. ANDERSON:</p> <p>9 Q. Do you?</p> <p>10 A. I have.</p> <p>11 Q. Okay. And what is that opinion, Dr. Klinge?</p> <p>12 A. The Prolift carries unnecessary risk and, 13 therefore, it's unsafe.</p> <p>14 Q. Doctor, did we prepare a slide for the jury 15 regarding your opinions of what you consider to be 16 the critical design defects in the Prolift?</p> <p>17 A. Yes.</p> <p>18 - - -</p> <p>19 (Plaintiff's Demonstrative Exhibit No. P3362, 20 PowerPoint slide entitled "Prolift Unsafe/Defective 21 Mesh Design", was marked for identification.)</p> <p>22 - - -</p> <p>23 MR. ANDERSON: Okay. If we could show that. 24 That is Plaintiff's Demonstrative 3362.</p>	<p>1 design that avoids this collapse under forces would 2 be much safer, and there is no need that you bring in 3 a mesh that shows this roping. There is no need, 4 and, therefore, all these three points are 5 unnecessary risks.</p> <p>6 Q. After all of your review of the thousands of 7 pages of depositions, the internal Ethicon documents, 8 all the things that we've been just covered 9 throughout your testimony today as well as your work 10 with Ethicon as a consultant for ten years and over 11 20 years of work in the field, do you have an opinion 12 to a reasonable degree of medical and scientific 13 certainty as to whether the Prolift was safely 14 designed to be permanently implanted in a woman's 15 pelvis?</p> <p>16 A. Yes.</p> <p>17 MR. THOMAS: Objection; foundation, 18 expertise.</p> <p>19 BY MR. ANDERSON:</p> <p>20 Q. Now answer the question.</p> <p>21 A. Yes.</p> <p>22 Q. And what is that opinion, Doctor?</p> <p>23 MR. THOMAS: Same objection.</p> <p>24 BY MR. ANDERSON:</p>

Page 82	Page 84
<p>1 Q. Now go.</p> <p>2 A. Because it carries unnecessary risk. It is</p> <p>3 designed unsafe and defective.</p> <p>4 MR. ANDERSON: Thank you. No further</p> <p>5 questions at this time.</p> <p>6 THE VIDEOGRAPHER: We are off the record.</p> <p>7 The time is 10:22 a.m.</p> <p>8 (A recess was taken from 10:22 a.m. until 10:33 a.m.)</p> <p>9 THE VIDEOGRAPHER: This marks beginning of</p> <p>10 Video Number 2. We are back on the record. The</p> <p>11 time is 10:33 a.m.</p> <p>12 CROSS-EXAMINATION</p> <p>13 BY MR. THOMAS:</p> <p>14 Q. Good morning, Dr. Klinge.</p> <p>15 A. Good morning.</p> <p>16 Q. You're an expert that's been retained by</p> <p>17 Mr. Anderson in this case; is that correct? Expert</p> <p>18 witness?</p> <p>19 A. Yes.</p> <p>20 Q. And you're paid for the time that you spend</p> <p>21 working on this matter?</p> <p>22 A. Yes.</p> <p>23 Q. And you're paid at the rate of \$500 an hour;</p> <p>24 is that right?</p>	<p>1 you were a practicing surgeon with a focus on</p> <p>2 abdominal hernia repairs; correct?</p> <p>3 A. No. Ah.</p> <p>4 Q. What?</p> <p>5 A. Yeah. So I just understand. I was an</p> <p>6 abdominal surgeon with the focus on hernia surgery.</p> <p>7 That is okay, yeah.</p> <p>8 Q. Okay. Fine. Thank you.</p> <p>9 And I'm not trying to trick you. If you</p> <p>10 don't understand my question, let me know, and I'll</p> <p>11 try to rephrase it. I know that English is not your</p> <p>12 first language, and I'll do the first I can.</p> <p>13 A. And I am not sure every time.</p> <p>14 Q. And I speak West Virginian. I don't speak</p> <p>15 German.</p> <p>16 Doctor, you've not performed surgery since</p> <p>17 2006, have you?</p> <p>18 A. Not in humans.</p> <p>19 Q. Okay. And prior to 2006, you treated</p> <p>20 hernias?</p> <p>21 A. Yes.</p> <p>22 Q. And a hernia is essentially an organ pushing</p> <p>23 through the abdominal wall; correct?</p> <p>24 A. Not always.</p>
<p>1 A. Yes.</p> <p>2 Q. How much money have you been paid to work on</p> <p>3 this case?</p> <p>4 MR. ANDERSON: Objection. You mean Bellew?</p> <p>5 MR. THOMAS: Yes.</p> <p>6 MR. ANDERSON: The Bellew case.</p> <p>7 THE WITNESS: It's about \$20,000, included</p> <p>8 the tax. In Germany you have to reduce it almost</p> <p>9 by half.</p> <p>10 BY MR. THOMAS:</p> <p>11 Q. Okay. And in preparation for your deposition</p> <p>12 today, you met with Mr. Anderson?</p> <p>13 A. Yes.</p> <p>14 Q. And how many days did you meet with</p> <p>15 Mr. Anderson?</p> <p>16 A. Three days.</p> <p>17 Q. Okay. And how many hours did you spend with</p> <p>18 Mr. Anderson in preparation for your deposition?</p> <p>19 A. Six hours a day.</p> <p>20 Q. So about 18 hours?</p> <p>21 A. Maybe.</p> <p>22 Q. So about \$9,000; correct?</p> <p>23 A. Yeah.</p> <p>24 Q. All right. Now, from the mid-1990s to 2006,</p>	<p>1 Page 83</p> <p>1 Q. Why can you not describe a hernia as an organ</p> <p>2 pushing through the abdominal wall?</p> <p>3 A. Because there are hernias, for example, close</p> <p>4 to the esophagus, through the diaphragm, where you</p> <p>5 have a hernia, but it is not a defect in the</p> <p>6 abdominal wall.</p> <p>7 Q. Okay. Well, you could repair hernias with</p> <p>8 sutures; is that correct?</p> <p>9 A. You can try to repair it by sutures, yes.</p> <p>10 Q. And sutures are sometimes called stitches?</p> <p>11 A. Yes.</p> <p>12 Q. And sutures and stitches are the Prolene that</p> <p>13 you showed to the jury on direct examination;</p> <p>14 correct?</p> <p>15 A. There are many kind of different sutures,</p> <p>16 different suture materials, and one of the suture</p> <p>17 material is Prolene.</p> <p>18 Q. And when you repair a hernia with sutures,</p> <p>19 you basically put the tissue back in place and then</p> <p>20 support it with the stitches; correct?</p> <p>21 A. The stitches are supported to keep the</p> <p>22 approximation of the tissues together, yeah.</p> <p>23 Q. Okay. And you can also treat hernias with</p> <p>24 surgical mesh; correct?</p>

Page 86	Page 88
<p>1 A. Yes.</p> <p>2 Q. And you can repair hernias with polypropylene</p> <p>3 mesh; correct?</p> <p>4 A. Yes.</p> <p>5 Q. There are about 20 million surgical mesh</p> <p>6 implantations every year; true?</p> <p>7 A. That is said by Saunders in his reference.</p> <p>8 Whether it's true, I didn't count it.</p> <p>9 Q. And abdominal hernia repair is the most</p> <p>10 frequently performed operation and surgery; correct?</p> <p>11 A. That is correct.</p> <p>12 Q. And the use of mesh to repair hernias is an</p> <p>13 important option for patients; true?</p> <p>14 A. Yes.</p> <p>15 Q. Polypropylene is the most widely used mesh</p> <p>16 for hernia repair; true?</p> <p>17 A. That should be true.</p> <p>18 Q. And mesh implants made of polypropylene have</p> <p>19 been used in the human body since 1963; true?</p> <p>20 A. That is true.</p> <p>21 Q. And Ethicon began selling Prolene mesh for</p> <p>22 hernia repair in 1974?</p> <p>23 A. Yeah.</p> <p>24 Q. And the Prolene mesh that's used to repair</p>	<p>1 Q. And we don't have a Prolift here, but the</p> <p>2 Prolift itself does not look like Exhibit 3364;</p> <p>3 correct?</p> <p>4 A. Yes.</p> <p>5 Q. Now, the hernia meshes that you used to</p> <p>6 repair hernias are often bigger than the meshes used</p> <p>7 in the pelvic floor to repair a pelvic organ</p> <p>8 prolapse; correct?</p> <p>9 A. The meshes can be bigger, but the area for</p> <p>10 implantation is completely different.</p> <p>11 Q. So are you telling the jury that implanting a</p> <p>12 mesh in the abdominal area is different from</p> <p>13 implanting a mesh in the pelvic floor?</p> <p>14 MR. ANDERSON: Objection.</p> <p>15 THE WITNESS: Yes.</p> <p>16 MR. ANDERSON: Go ahead.</p> <p>17 BY MR. THOMAS:</p> <p>18 Q. Stay with me, though, for a minute. But the</p> <p>19 amount of mesh that you implant in the abdominal area</p> <p>20 to repair hernias is often much more than the amount</p> <p>21 of mesh that's used in this anterior Prolift that you</p> <p>22 have described in P3364; correct?</p> <p>23 A. It was correct before we developed together</p> <p>24 with Ethicon these large pore meshes, which have a</p>
Page 87	Page 89
<p>1 hernias is the same material that is used to make</p> <p>2 Prolene soft in the Prolift; correct?</p> <p>3 A. Please, can you --</p> <p>4 Q. Prolene mesh used in hernia repair is made of</p> <p>5 the same polypropylene material that is used to make</p> <p>6 Prolene soft for use in the Prolift?</p> <p>7 A. I think so, yeah.</p> <p>8 Q. Now, you started implanting polypropylene</p> <p>9 mesh for hernia repair in the early 1990s; true?</p> <p>10 A. Yes.</p> <p>11 Q. And you performed about 200 hernia repairs</p> <p>12 using mesh; correct?</p> <p>13 A. Yes.</p> <p>14 Q. Now, a minute ago you showed the jury</p> <p>15 Plaintiff's Exhibit 3364, which is the amount of</p> <p>16 polypropylene that, if taken apart, the Prolift would</p> <p>17 have in it; correct?</p> <p>18 A. Yes.</p> <p>19 Q. Well, just so it's clear, you never implant</p> <p>20 polypropylene in that form into a body, do you?</p> <p>21 A. No.</p> <p>22 Q. The polypropylene is woven or knitted into a</p> <p>23 mesh so it can be implanted; correct?</p> <p>24 A. Yes.</p>	<p>1 reduced amount of material. We could reduce the</p> <p>2 amount of polypropylene to 30 percent of these</p> <p>3 heavyweight small pore meshes, and, therefore, it is</p> <p>4 difficult. It depends from -- from the specific size</p> <p>5 of the mesh. Then you can do this calculation and</p> <p>6 look whether it exactly fits or whether it's a little</p> <p>7 bit more.</p> <p>8 Q. Meshes that you used before 2006 to implant</p> <p>9 into humans for the repair of hernias had more</p> <p>10 polypropylene in them than the polypropylene that you</p> <p>11 showed the jury in 3364; correct?</p> <p>12 A. 2006 you said?</p> <p>13 Q. Before 2006. You implanted meshes --</p> <p>14 A. We --</p> <p>15 Q. -- some meshes that had more polypropylene</p> <p>16 than is present in 3364.</p> <p>17 A. After our development of Vypro of these large</p> <p>18 pore meshes with Ethicon, we only use these</p> <p>19 material-reduced methods; and, therefore, the use of</p> <p>20 this huge amount of material was very, very rare.</p> <p>21 Q. You know today that mesh is used in the</p> <p>22 repair of hernias by a doctor every single day, in</p> <p>23 Germany, in the United States, everywhere around the</p> <p>24 world that has more mesh than is present in 3364,</p>

Page 90	Page 92
<p>1 don't you?</p> <p>2 A. I know that in Germany 90 percent -- more</p> <p>3 than 90 percent of the meshes used for hernia repair</p> <p>4 are large pore meshes.</p> <p>5 Q. And what meshes are those specifically?</p> <p>6 A. These are Ultrapro. Ultrapro is the leading</p> <p>7 from Ethicon.</p> <p>8 Q. Okay. Are you saying Ultrapro is appropriate</p> <p>9 for the pelvic floor?</p> <p>10 A. No.</p> <p>11 Q. So just so your testimony is clear, it's not</p> <p>12 your opinion that Ultrapro is an appropriate mesh to</p> <p>13 treat pelvic organ prolapse in the pelvic floor;</p> <p>14 true?</p> <p>15 A. If you stick to the third point we presented</p> <p>16 there, that it has to prevent a pore collapse -- and</p> <p>17 Ultrapro obviously does not prevent a pore collapse</p> <p>18 when applied to forces; therefore, it is not the best</p> <p>19 idea to use Ultrapro in this -- for this indication,</p> <p>20 yes.</p> <p>21 Q. It's true that you do not have the opinion</p> <p>22 that Ultrapro is a reasonable alternative design for</p> <p>23 the use of mesh in the treatment of pelvic organ</p> <p>24 prolapse; true?</p>	<p>1 Q. Turn to page 89 of the deposition, please.</p> <p>2 MR. ANDERSON: I think you gave me two</p> <p>3 copies, Counsel. Yeah. You gave me --</p> <p>4 MR. THOMAS: I think there's two days.</p> <p>5 MR. ANDERSON: Oh, you're going to need both.</p> <p>6 THE WITNESS: 98?</p> <p>7 BY MR. THOMAS:</p> <p>8 Q. Page 89, line 16. You there?</p> <p>9 "QUESTION: And, Doctor, in the early '90s</p> <p>10 the physicians didn't understand all of the</p> <p>11 biomechanical demands of the abdomen; is that</p> <p>12 correct?</p> <p>13 "ANSWER: There was limited knowledge about</p> <p>14 the biomechanics of the abdomen."</p> <p>15 Did I read that correctly?</p> <p>16 MR. ANDERSON: Excuse me. I will object.</p> <p>17 That is not the same question you asked. You</p> <p>18 asked, "Do you know everything," and here you</p> <p>19 changed the question from this to what it was in</p> <p>20 the deposition. So if we were at sidebar, I</p> <p>21 would have pointed that out to the judge.</p> <p>22 MR. THOMAS: And I understand your objection.</p> <p>23 BY MR. THOMAS:</p> <p>24 Q. Did I read that correctly?</p>
<p style="text-align: center;">Page 91</p> <p>1 MR. ANDERSON: Objection to form.</p> <p>2 THE WITNESS: As it carries unnecessary risk,</p> <p>3 I am sure that it is not a safe alternative.</p> <p>4 BY MR. THOMAS:</p> <p>5 Q. Okay. Now, when you started implanting mesh</p> <p>6 for hernia repair, you didn't understand all of the</p> <p>7 biomechanical demands of the abdomen; true?</p> <p>8 A. It is a permanent learning that I have when I</p> <p>9 started surgery. I don't know, but I permanently</p> <p>10 learned about it. And we learned a lot about these</p> <p>11 meshes, and, of course, when we started to make this</p> <p>12 research, we didn't know everything.</p> <p>13 Q. Are you able to answer my question yes or no?</p> <p>14 Let me ask it again.</p> <p>15 When you started implanting mesh for hernia</p> <p>16 repair, you didn't understand all of the</p> <p>17 biomechanical demands of the abdomen; true?</p> <p>18 A. What do you think of "all"?</p> <p>19 Q. Doctor, let me hand you your deposition that</p> <p>20 you gave.</p> <p>21 I'm sorry. It's the wrong one.</p> <p>22 No. I was right.</p> <p>23 MR. ANDERSON: Thank you, Counsel.</p> <p>24 BY MR. THOMAS:</p>	<p style="text-align: center;">Page 93</p> <p>1 A. Yeah.</p> <p>2 Q. Okay.</p> <p>3 MR. ANDERSON: It's an inappropriate use of</p> <p>4 the deposition, so that's my objection.</p> <p>5 MR. THOMAS: And you stated it clearly.</p> <p>6 BY MR. THOMAS:</p> <p>7 Q. And, Doctor, it's clear that in the '90s</p> <p>8 physicians didn't understand all of the biomechanical</p> <p>9 demands of the abdomen; true?</p> <p>10 A. There was limited knowledge about the</p> <p>11 biomechanics of the abdomen. Still open questions.</p> <p>12 Q. Okay. And when you were performing hernia</p> <p>13 surgery, it was important for you that the patient</p> <p>14 understand whether the benefits of that hernia</p> <p>15 surgery outweighed the risks of that hernia surgery;</p> <p>16 correct?</p> <p>17 A. That is correct.</p> <p>18 Q. And it's your job as a doctor to explain the</p> <p>19 risks of hernia surgery to the patient so the patient</p> <p>20 can make that informed decision; correct?</p> <p>21 A. Yes.</p> <p>22 Q. And it's true, Doctor, that any surgery has</p> <p>23 risks?</p> <p>24 A. Which type of risks do you think?</p>

Page 94	Page 96
<p>1 Q. Well, is it true that every hernia surgery 2 has risks?</p> <p>3 A. Has some risks.</p> <p>4 Q. And it's your job to tell a patient about 5 those risks so that they can make a decision about 6 whether to have the surgery; correct?</p> <p>7 A. I have to tell him not that there are 8 possible ways to get some complication, but I have to 9 give him the information that he gets a good estimate 10 how big the risk is, whether there is an alternative 11 with a less risk and what is the benefit.</p> <p>12 Q. And --</p> <p>13 A. So is it a necessary risk or is it an 14 unnecessary risk? And all this together I have to 15 discuss with the patient. It is not so simple to say 16 there are some risks.</p> <p>17 Q. And you tell the patient that there is a 18 lifelong risk of infection from that mesh implant, 19 wouldn't you?</p> <p>20 A. From the moment we know there is a -- that we 21 learn that there was this permanent inflammation that 22 you have a lifelong risk for infection. You have an 23 implant. They received an implant. It's not a 24 tissue repair. They received a plastic implant for</p>	<p>1 A. This topic surely is mentioned with the 2 patient, that chronic pain may be a serious 3 complication after operation, yes.</p> <p>4 Q. And when you say late onset, that means that 5 this pain does not manifest itself until after the 6 surgery sometime; correct?</p> <p>7 A. Yes.</p> <p>8 Q. And you also tell patients that hernia mesh 9 is difficult to remove; true?</p> <p>10 A. Yes.</p> <p>11 Q. And you talk to a patient about a risk of 12 hernia recurrence?</p> <p>13 A. Yes.</p> <p>14 Q. And a hernia recurrence means that the mesh 15 repair did not work and the hernia repair comes back; 16 correct -- excuse me, the hernia comes back; is that 17 correct?</p> <p>18 A. There are different definitions of 19 recurrence, and where the hernia comes back, whether 20 it's really a problem that the mesh doesn't work, 21 whether it's a new hernia that is for the patient a 22 recurrence. So it is not so simple, but we are 23 discussing the manifestation of another hernia 24 despite using a mesh.</p>
<p>1 the rest of their lives.</p> <p>2 Q. And anytime you have a plastic implant, 3 there's a risk, a lifelong risk of an infection; 4 true?</p> <p>5 A. Yes.</p> <p>6 Q. And that would be for a hip or for a knee 7 just as well as a mesh; correct?</p> <p>8 A. But the numbers are different, and it is 9 different to treat it.</p> <p>10 Q. Answer to my -- Doctor, it's fair to say that 11 there's a lifelong risk of infection from mesh, just 12 like there's a lifelong risk of infection from a hip 13 implant or a knee implant? Yes or no.</p> <p>14 MR. ANDERSON: Objection; beyond the scope of 15 cross -- beyond the scope of direct.</p> <p>16 THE WITNESS: If you are thinking of the 17 principal possibility of a lifelong risk to get 18 an infection, yes.</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. Thank you.</p> <p>21 And when you're talking to a patient about 22 the risks of hernia repair, you talk to a patient 23 about the risk of a late onset of chronic pain; 24 correct?</p>	<p>1 Q. And a patient needs to know that there's a 2 risk that the surgery won't work; correct?</p> <p>3 A. Yes.</p> <p>4 Q. And you talk to a patient who is looking at a 5 potential hernia repair with mesh about the risk of 6 mesh shrinkage; correct?</p> <p>7 A. Yes.</p> <p>8 Q. And any mesh will have a shrinkage or 9 contracture rate of at least 20 percent; correct?</p> <p>10 A. At least 20 percent? The difference is the 11 extent of this one.</p> <p>12 Q. Any -- any mesh -- it's true that any mesh 13 will have a shrinkage or contracture rate of at least 14 20 percent; correct?</p> <p>15 A. There may be some conditions where it's a 16 little bit lower, but, yeah, sure, more or less it 17 is. You have to assume a contraction of 20 percent.</p> <p>18 Q. And when you were treating patients for 19 hernia repairs, you explained all of these risks to 20 the patient so the patient would understand?</p> <p>21 A. But in a completely different way.</p> <p>22 Q. Is that true?</p> <p>23 A. I explained these risks to the patients.</p> <p>24 Q. So when you used polypropylene mesh for</p>

Page 98	Page 100
<p>1 hernia repair, you believed that the benefits of that</p> <p>2 mesh outweighed any risks to your patient; true?</p> <p>3 A. In some specific patients in some specific</p> <p>4 conditions where we are discussing the alternatives,</p> <p>5 we are discussing the risks of the patient's</p> <p>6 conditions, the risk of the procedure, the risk of</p> <p>7 the biomaterials, all this together will end up in</p> <p>8 the risk-benefit ratio. And when you have all this</p> <p>9 information, how often something occurs, then you can</p> <p>10 discuss it with the patient and you can make your</p> <p>11 decision, yes.</p> <p>12 Q. Well, when you recommended mesh to a patient</p> <p>13 for the repair of their hernia, you believed that the</p> <p>14 mesh that you were going to use, the benefits of that</p> <p>15 mesh outweighed the risk to the patients; true?</p> <p>16 A. In those patients where I am using meshes, I</p> <p>17 have been using meshes, the decision of me and the</p> <p>18 patient was that in this case the use of a specific</p> <p>19 mesh in a specific way outweighs the risks.</p> <p>20 Q. Okay. Now, over the last 20 years, there are</p> <p>21 millions of people on earth walking around with mesh</p> <p>22 in their body, and a large percentage of those meshes</p> <p>23 are either polypropylene or they contain</p> <p>24 polypropylene; true?</p>	<p>1 A. Yes.</p> <p>2 Q. And the top left-hand corner, is that the</p> <p>3 area of mesh that you were describing in your direct</p> <p>4 examination?</p> <p>5 A. Yes.</p> <p>6 Q. And that mesh has -- is covered with tissue;</p> <p>7 correct?</p> <p>8 A. Yes.</p> <p>9 Q. And that mesh has been stored in</p> <p>10 formaldehyde; correct?</p> <p>11 A. Yes.</p> <p>12 Q. And you have not measured that mesh to</p> <p>13 determine the extent to which any pores in that mesh</p> <p>14 have collapsed, have you?</p> <p>15 A. Not specifically this mesh.</p> <p>16 Q. Thank you.</p> <p>17 As a matter of fact, you have not performed</p> <p>18 any analysis on the mesh specific to Ms. Bellew;</p> <p>19 correct?</p> <p>20 A. Specifically, yeah.</p> <p>21 Q. Now, you have not ever performed surgery for</p> <p>22 the repair of pelvic organ prolapse; correct?</p> <p>23 A. That is correct.</p> <p>24 Q. And we talked about the Prolift before.</p>
<p style="text-align: center;">Page 99</p> <p>1 A. Sure.</p> <p>2 Q. Yeah. Now, you've never treated the</p> <p>3 plaintiff in this case; correct?</p> <p>4 A. That is correct.</p> <p>5 Q. And you've never examined the plaintiff in</p> <p>6 this case; correct?</p> <p>7 A. That is correct.</p> <p>8 Q. And you have never rendered any medical</p> <p>9 diagnosis specific to the plaintiff in this case;</p> <p>10 correct?</p> <p>11 A. That is correct.</p> <p>12 Q. And you have never examined the actual mesh</p> <p>13 explanted from the plaintiff in this case; correct?</p> <p>14 Other than the photograph you looked at?</p> <p>15 A. I think so, yeah.</p> <p>16 Q. Now, I want to look at that photograph that</p> <p>17 Mr. Anderson showed you. Do you have it in front of</p> <p>18 you? Exhibit P3356.</p> <p>19 Do you have that, Dr. Klinge?</p> <p>20 A. Yes.</p> <p>21 Q. Now --</p> <p>22 A. I see.</p> <p>23 Q. In the top left-hand corner -- you understand</p> <p>24 this to be a mesh explant from Mrs. Bellew?</p>	<p style="text-align: center;">Page 101</p> <p>1 You've never used a Prolift in any surgery; correct?</p> <p>2 A. That is correct.</p> <p>3 Q. And do you know the tools that are used to</p> <p>4 place Prolift?</p> <p>5 A. I've seen it on the video.</p> <p>6 Q. There's a trocar?</p> <p>7 A. Yes.</p> <p>8 Q. And there's a cannula; correct?</p> <p>9 A. Yes.</p> <p>10 Q. You've never placed a mesh with trocars, have</p> <p>11 you?</p> <p>12 A. No.</p> <p>13 Q. You've never placed a mesh with cannulas,</p> <p>14 have you?</p> <p>15 A. No.</p> <p>16 Q. You've never placed a mesh using the same</p> <p>17 tools as Prolift; correct?</p> <p>18 A. That is correct.</p> <p>19 Q. Now, you were shown Exhibit 3361. Could you</p> <p>20 get that in front of you, please.</p> <p>21 MR. THOMAS: Could you pull that up, please,</p> <p>22 3361, so the jury can see it?</p> <p>23 BY MR. THOMAS:</p> <p>24 Q. And this is the slide that you talked about</p>

Page 102	Page 104
<p>1 on direct examination, and this is a surgical 2 procedure involving the Prolift; correct? 3 A. Yes. 4 Q. And it uses cannulas; correct? 5 A. Yes. 6 Q. And it uses trocars; correct? 7 A. Yes. 8 Q. And you've never used either one of those; 9 correct? 10 A. Yes. 11 Q. And you understand that the mesh is to be 12 placed tension-free inside the body; correct? 13 A. What do you mean by is said or -- 14 Q. Do you know that -- do you know that a 15 surgeon is to place the Prolift in the body 16 tension-free? Do you know that? 17 A. There are some ideas that it should be done 18 tension-free, but obviously it is not possible to 19 place it tension-free; therefore, there is no 20 measurement that it is done tension-free. There 21 is -- it's not a fact. 22 Q. But you have not done one; correct? 23 A. Yes. 24 Q. It's correct that you have not done one?</p>	<p>1 able to investigate, we saw this deformation, this 2 roping in all of these explants, wherever they were 3 taken. It's not a phenomenon that is outside the 4 body. It's inside the body. 5 Q. You've not seen it yourself, have you, 6 Doctor? 7 A. In this case, not. 8 Q. Okay. 9 A. Only in the video I've seen it. 10 Q. And the only video that you've seen of a 11 Prolift repair is the one that you just discussed; 12 correct? 13 A. That is a video made by Ethicon -- 14 Q. Okay. 15 A. -- as a teaching video. 16 Q. And you don't have any basis to give an 17 opinion as to what the mesh looks like in the body, 18 do you? 19 MR. ANDERSON: Objection. 20 THE WITNESS: If you -- 21 BY MR. THOMAS: 22 Q. Is that yes or no? You can tell me yes or no 23 and then tell me what it is. 24 A. Please then.</p>
<p style="text-align: center;">Page 103</p> <p>1 A. It is correct that I never did it. 2 Q. Okay. You've never tried to place mesh 3 tension-free inside a woman; correct? 4 A. I -- the abdominal wall surgery, the use of 5 meshes, is supposed to be in a tension-free area. We 6 know that's -- and I did it in woman. 7 Q. Okay. But not in a pelvic floor? 8 A. Not in the pelvic floor. 9 Q. Okay. And when the Prolift is placed, it 10 goes through cannulas; correct? 11 A. Yes. 12 Q. And that allows for the smooth passage of the 13 mesh through the cannulas; correct? 14 A. It is supposed that you need some forces, 15 according to the internal documents from Ethicon. It 16 is supposed that you need some forces to do so. 17 Q. And you don't know what this mesh looks like 18 inside of the person on whom this surgery is being 19 performed, do you? 20 A. In the video you have it -- a view from 21 inside, and it appears -- though the quality is not 22 very good for these slides, but it appears as if 23 these -- this mesh in the video is looking curled 24 even inside; and from all the explants that we were</p>	<p style="text-align: center;">Page 105</p> <p>1 Q. Do you have any basis to understand what the 2 mesh looks like in the body after it's implanted? 3 A. I have a basis, yes. 4 Q. And what is that? 5 A. This basis is our explants, our -- the 6 visualization of many operations that have been shown 7 on the conference where you see it that is the 8 appearance of the arms for Prolift total, Prolift 9 posterior. When you're looking to all of these 10 teaching videos, you always will see that the mesh is 11 not longer laying there in a flat way, but they 12 showed this roping. You can find it almost every -- 13 in every video and every transmission of an 14 operation. 15 Q. On the outside? 16 A. No. Before -- sometimes you are able to see 17 the arms before closing all wounds, or sometimes you 18 may make some laparoscopy looking from inside. 19 Q. Now, you're not an expert in pelvic floor 20 surgery with regards to the surgical procedure used 21 to treat pelvic organ prolapse; true? 22 A. In regard to surgical procedure, it's true. 23 Q. And you're not a specialist for finding the 24 best indication for a mesh in the pelvic floor; true?</p>

Page 106	Page 108
1 A. That is true.	1 "QUESTION: You've not studied the pelvic
2 Q. And you've never consulted with Ethicon on	2 floor forces in a human; correct?
3 issues of pelvic organ prolapse; true?	3 "ANSWER: That is correct."
4 A. That is true.	4 Did I read that correctly?
5 Q. Now, you're not an obstetrician; true?	5 A. Yes.
6 A. Please, what?	6 Q. Thank you.
7 Q. You're not an obstetrician?	7 Now, you agree that mesh is an important
8 A. What is an obste --	8 option for patients in pelvic floor repair; correct?
9 Q. Baby doctor.	9 A. In some patients, yes.
10 A. No, I'm not a baby doctor.	10 Q. And you agree that polypropylene is an
11 Q. You're not an obstetrician?	11 appropriate use in pelvic floor if you have the right
12 A. Okay. Yeah. Yeah.	12 construction of that polypropylene; correct?
13 Q. You're not a gynecologist?	13 A. If it's a right construction for this
14 A. I'm not.	14 specific purpose, yeah, it can be.
15 Q. You're not a urologist?	15 Q. Okay. And 91 percent of all gynecological
16 A. I'm not.	16 nonabsorbable meshes are polypropylene; correct?
17 Q. And you're not a urogynecologist; correct?	17 A. It should be, correct. We never -- I never
18 A. I'm not.	18 analyzed or counted it.
19 Q. And you've never completed a fellowship or	19 Q. Now, over the years you talked about your
20 residency in those fields; correct?	20 work from Ethicon. Ethicon paid you for your work,
21 A. That is correct.	21 didn't they?
22 Q. And you have never studied the pelvic	22 A. In the years from 2000 to 2005, yes. In the
23 forces -- pelvic floor forces in a human; correct?	23 years before, no.
24 A. We tried. We tried in some research projects	24 Q. And you received royalties from Ethicon for
Page 107	Page 109
1 to define the -- or to learn about the anatomy and	1 sales of Vypro; correct?
2 the forces.	2 A. In these -- this is the payment you're
3 Q. But you -- did you ever complete the study of	3 talking of. This is in the years from 2000 until
4 pelvic forces in the human?	4 2005. I got something like royalties for the selling
5 A. We completed some of the studies, and I guess	5 of Vypro and Ultrapro.
6 some of this already has been published in a	6 Q. And so every time Ethicon sold a Vypro and an
7 peer-reviewed literature, but of course we are not	7 Ultrapro, you earned money; correct?
8 finished with all our studies in this field.	8 A. Yes.
9 Q. Let me show you another transcript of	9 Q. You earned about 20,000€ a year from
10 testimony, please, and direct your attention to page	10 royalties from Ethicon from 2000 to 2005; is that
11 3497.	11 correct?
12 A. 47?	12 A. That is correct.
13 Q. 3497, line 15.	13 Q. Now, you received no royalties for the sales
14 A. 3497.	14 of Prolene mesh; correct? Prolene Soft Mesh.
15 MR. ANDERSON: And I'll just place an	15 A. Yes.
16 objection on the record. This is outside the	16 Q. I want to go back to another exhibit that you
17 scope of direct. Didn't talk about pelvic	17 talked about on direct, and it's Plaintiff's Exhibit
18 forces.	18 0697. Do you have that?
19 What's your page?	19 A. Not yet.
20 MR. THOMAS: 3497.	20 Q. 0697 is your 2013 study.
21 BY MR. THOMAS:	21 Do you have that now?
22 Q. Do you have it, Doctor?	22 A. Yes.
23 A. Yes.	23 Q. And Plaintiff's Exhibit 0697 was published in
24 Q. Line 15.	24 2013?

Page 110	Page 112
1 A. Yes.	1 Gynemesh PS from polypropylene to a DynaMesh made of
2 Q. Now, in this study in 2013, you compare	2 PVDF in this specific -- two specific meshes.
3 Prolift and Prolift+M with DynaMesh; correct?	3 Q. And just so the jury understands, DynaMesh is
4 A. That is correct.	4 manufactured by FEG; correct?
5 Q. And you and Mr. Mühl tested this -- these	5 A. Yes.
6 meshes on the same machine that you conducted your	6 Q. And you, at the time of this study, were a
7 test back in 2007; correct?	7 paid consultant for FEG; correct?
8 A. Yes.	8 A. Yes.
9 Q. And the machine that you developed in 2007	9 Q. Now, in the first paragraph of this study --
10 was fabricated in part by a company known as FEG;	10 excuse me, in the abstract in this study, you note on
11 correct?	11 the right side --
12 A. Please, can you -- can you please repeat it.	12 MR. THOMAS: Can you bring that up, please?
13 MR. THOMAS: Can you read that back, please.	13 It's 0697.
14 THE COURT REPORTER: "And the machine that	14 MR. KAUFFMANN: Which page?
15 you developed in 2007 was fabricated in part by a	15 MR. THOMAS: Front page. Excuse me. Let's
16 company known as FEG; correct?"	16 go to page -- the third page of that article.
17 THE WITNESS: I don't think they fabricated	17 Under Prolift+M system Gynemesh and Ultrapro,
18 any part of this machine.	18 first sentence.
19 BY MR. THOMAS:	19 BY MR. THOMAS:
20 Q. And what do you base that on?	20 Q. "Without any strain, the effective porosity
21 A. Because the FEG makes meshes and doesn't make	21 was 57.5 percent, and the majority of pores had a
22 any computer hardware, photograph, image maker, so	22 diameter of larger than 100 microns" -- "1,000
23 nothing -- no component of this machine can be done	23 microns."
24 by the FEG.	24 Correct?
Page 111	Page 113
1 Q. Okay.	1 A. Prolift+M, yeah. Yeah. You read it
2 A. So I think they -- Professor Mühl bought it	2 correctly.
3 from -- or has made it from their own engineers from	3 Q. Okay. And back on the first page in the
4 the university.	4 abstract on the right side, you identify the fact
5 Q. Okay. Have you read the depositions of	5 that Prolift in tension-free can be considered a
6 Professor Mühl?	6 large pore Class I mesh; correct?
7 A. I guess I have, yeah.	7 A. Yes. It's one of bigger -- it has one of the
8 Q. Okay. Did you recall any testimony he gave	8 biggest pores of all mesh available.
9 in that regard?	9 Q. And down at the bottom you say that both
10 A. No.	10 meshes -- this is on the right side of the first
11 Q. All right. When you did your testing back in	11 page.
12 2005 to 2007 and you developed this machine, did you	12 "Both meshes can be classified as large pore
13 do it in conjunction with the FEG?	13 Class I mesh with an effective porosity that is
14 A. Yes. It was a -- it was a funded project by	14 sufficient to prevent bridging of scar tissue
15 the ministry together with the FEG and Professor	15 throughout the entire pore."
16 Mühl, yeah.	16 Correct?
17 Q. And the FEG manufactures meshes?	17 A. I didn't -- didn't -- couldn't follow where
18 A. Yes.	18 you have been reading.
19 Q. And the FEG makes PVDF meshes; correct?	19 Q. I'm down --
20 A. Yes.	20 MR. ANDERSON: You changed. He was down in
21 Q. And PVDF meshes are the meshes that you	21 the abstract. You're moving down.
22 compare -- used to compare the other meshes in the	22 BY MR. THOMAS:
23 study; correct?	23 Q. Down on the right side, about two-thirds of
24 A. We made a comparison between this specific	24 the way on the right. "The Gynemesh PS is identical

Page 114	Page 116
<p>1 to the Prolene Soft Mesh for hernia repair, and the 2 textile structure of the Prolift+M system is copied 3 from the Ultrapro hernia mesh."</p> <p>4 A. Is identical, yes.</p> <p>5 Q. "Both meshes can be classified as large pore 6 Class I mesh with an effective porosity that is 7 sufficient to prevent bridging of scar tissue 8 throughout the entire pore."</p> <p>9 That's true?</p> <p>10 A. You read -- no, that's not true, but you read 11 it correctly. It's not true if you applied some 12 forces to it.</p> <p>13 Q. Okay. Well, this --</p> <p>14 A. This is just restricted to the situation 15 where you don't apply any forces.</p> <p>16 Q. Okay. And it's only if you apply forces to 17 it that, as far as you're concerned, it loses the 18 adequate pore size to prevent against this bridging; 19 correct?</p> <p>20 A. Then, yes, it's correct that this mesh then 21 change to a small pore, dangerous high risk device.</p> <p>22 Q. All right. Now, the testing that you have in 23 Exhibit 0697, you were retained as a plaintiff's 24 expert at this time; correct?</p>	<p>1 Q. Where is your basketball net?</p> <p>2 A. We don't have ball.</p> <p>3 Q. Don't need a ball.</p> <p>4 A. Okay.</p> <p>5 MR. ANDERSON: Would you like to use my net, 6 Dave?</p> <p>7 MR. THOMAS: I would, please.</p> <p>8 BY MR. THOMAS:</p> <p>9 Q. I don't remember what number we attached to 10 this net, but I want to ask you some questions about 11 the net.</p> <p>12 You used the net to describe to the jury 13 forces that are present in the pelvic floor; correct?</p> <p>14 A. No. I want to demonstrate what happens to a 15 pore if you applied some forces.</p> <p>16 Q. Okay.</p> <p>17 A. And you see the pore collapse. That is a 18 fact.</p> <p>19 Q. Now, when you tested the mesh like you did in 20 Exhibit 0697, you attached one end of the mesh to one 21 point and then pulled it in one direction; correct?</p> <p>22 A. Yes.</p> <p>23 Q. And if you could show that to the jury. Hold 24 one end and pull.</p>
Page 115	Page 117
<p>1 A. I did not understand this.</p> <p>2 Q. You were a plaintiff's -- you were an expert 3 for Mr. Anderson at the time you did the work on this 4 paper; correct?</p> <p>5 A. Yes.</p> <p>6 Q. And you were paid for your time in connection 7 with this work; correct?</p> <p>8 A. Yes.</p> <p>9 Q. And you didn't disclose that in the study 10 that you were an expert for plaintiffs in litigation 11 against Ethicon at the time that you did this study; 12 correct?</p> <p>13 A. Yes.</p> <p>14 Q. And it's also correct that you didn't 15 disclose in this study that you were a consultant for 16 the FEG; correct?</p> <p>17 A. Yes.</p> <p>18 Q. And it's also correct that you show in this 19 article that the -- or purport to show that the 20 DynaMesh retains a better effective porosity than the 21 Ethicon mesh under strain; correct?</p> <p>22 A. We showed that there is an option to do it 23 without collapse of the pores, and this is done by 24 the DynaMesh. That was shown in the article.</p>	<p>1 A. (Complying.)</p> <p>2 Q. And that's how -- that's how you tested it in 3 your study; correct?</p> <p>4 A. Yeah. Similar to the way Ethicon did it.</p> <p>5 MR. THOMAS: Move to strike after "yes."</p> <p>6 BY MR. THOMAS:</p> <p>7 Q. And you applied weights of 100 grams to 1,000 8 grams to the other end of the mesh in order to get 9 your results; correct?</p> <p>10 A. If you're talking of this study, yes.</p> <p>11 Q. Now, in the body, mesh undergoes forces from 12 multiple directions, doesn't it?</p> <p>13 A. It depends whether it functions as a 14 replacement of ligaments or whether it is a function 15 as a flat area, but, of course, you always have 16 forces from all sides wherever you are in the world.</p> <p>17 But if you are thinking of ligaments, the relevant 18 forces are -- should be -- or should -- it should be 19 possible to estimate them if you're thinking of 20 uniaxial, from one direction.</p> <p>21 Q. And when you place the mesh in the body -- 22 spread out the net --</p> <p>23 A. (Complying.)</p> <p>24 Q. -- tissue goes into the pores; correct?</p>

Page 118	Page 120
<p>1 A. Yes.</p> <p>2 Q. And it's applied tension-free so that the 3 tissue in the pores is what actually holds the mesh 4 into place; correct?</p> <p>5 MR. ANDERSON: Objection.</p> <p>6 Go ahead.</p> <p>7 THE WITNESS: Yes.</p> <p>8 BY MR. THOMAS:</p> <p>9 Q. And you've not done any testing of mesh with 10 tissue in it, have you? Excuse me. Strike that.</p> <p>11 You have not done any effective porosity 12 testing of mesh with tissue in it, have you?</p> <p>13 A. We didn't do -- it is impossible to do it 14 with this machine, to have a testing of the effective 15 porosity, a measurement of the effective porosity 16 with tissue inside.</p> <p>17 Q. Okay. And you know that it's possible to 18 design a test that tests the forces on the mesh from 19 multiple directions, don't you?</p> <p>20 A. I know that there are experimental settings 21 doing this, but it is a -- it is impossible to model 22 the situation in a pelvis in -- with any of these 23 settings completely. It's -- every time -- 24 everything is just an arbitrary trial that you can</p>	<p>1 A. Yes.</p> <p>2 Q. And it's not only the one directional force 3 that you used in your test model; correct?</p> <p>4 A. The one direction force is the best 5 approximation for the ligaments, for the arms.</p> <p>6 Q. But my --</p> <p>7 A. Not for the others. I agree. Not for the 8 flat mesh area. Then it is not the best way.</p> <p>9 Q. And it's possible to design a test that 10 allows for mesh being pulled in multiple directions 11 and also to account for weight on the top of the 12 mesh?</p> <p>13 A. As I said, no. Not sufficiently. You can 14 design such a test where you put forces from various 15 directions, but the interpretation of these results 16 is very difficult; and overall as a setup to reflect 17 the situation in the body, it is insufficient.</p> <p>18 Q. As a matter of fact, the test that you did in 19 both 2007 and 2013 is insufficient to determine the 20 extent to which this test can be applied to the 21 development of better meshes; correct?</p> <p>22 A. No.</p> <p>23 Q. Let me show you -- go back to your study, 24 Plaintiff's 0697.</p>
<p>1 try to model it, but it's not -- never perfect.</p> <p>2 Q. But you agree it's possible to construct a 3 test that measured forces applied in different 4 directions of the mesh; correct?</p> <p>5 A. You can make a setting where you apply some 6 forces from two directions, but it never reflects a 7 situation of a mesh that is incorporated into tissue.</p> <p>8 Never.</p> <p>9 Q. So when --</p> <p>10 A. There's no way.</p> <p>11 Q. When you -- you can design a -- strike that.</p> <p>12 When mesh is implanted in the human body, the 13 stresses that are applied to that mesh are both 14 lengthwise, top to bottom, diagonally; correct?</p> <p>15 A. It depends from the location and of the 16 function and of the size of the mesh whether the 17 model has to include these differences or whether 18 it's possible to just think of one direction, and all 19 mechanical testing setups are insufficient or 20 computer simulations until now are insufficient to 21 model this.</p> <p>22 Q. Well, it's true that there are a variety of 23 forces that are applied to a mesh in placement in the 24 pelvic floor; correct?</p>	<p>1 In 2013, the last sentence of the abstract, 2 it says, "The clinical studies have to prove whether 3 devices with high porosity as well as high structural 4 stability can improve the patient's outcome."</p> <p>5 Did I read that correctly?</p> <p>6 A. Yes.</p> <p>7 Q. And in 2007 --</p> <p>8 MR. THOMAS: Can I have a sticker, please.</p> <p>9 I'm going to mark this as Klinge Trial 10 Deposition Exhibit Number 1.</p> <p>11 - - -</p> <p>12 (Klinge Trial Deposition Exhibit No. 1, 13 Article entitled "New Objective Measurement to 14 Characterize the Porosity of Textile Implants," Bates 15 stamped DX31026.1 through DX31026.8, was marked for 16 identification.)</p> <p>17 - - -</p> <p>18 BY MR. THOMAS:</p> <p>19 Q. Let me show you what I have marked as Klinge 20 Trial Deposition Exhibit Number 1.</p> <p>21 MR. ANDERSON: Thank you.</p> <p>22 Q. Klinge Trial Deposition Exhibit Number 1 is 23 the first study that you and Professor Mühl conducted 24 back in 2007; correct?</p>

Page 122	Page 124
1 A. Yes.	1 A. The problem that they are not there are
2 Q. And in this study, you and Professor Mühl did	2 because the old meshes, the small pore meshes, as
3 uniaxial testing on DynaMesh and other meshes	3 Prolift, they all belong to the category of these
4 manufactured in Europe; correct?	4 small pore thing.
5 A. Yes.	5 Q. Okay.
6 Q. And you found in 2007 that the DynaMesh	6 A. How we don't have sufficient explants from
7 retained its effective porosity and the other meshes	7 large pore materials with a high structural stability
8 did not; correct?	8 in the moment, but we are still collecting these
9 A. No.	9 materials.
10 Q. Not true?	10 Q. Can you answer my question yes or no? Let me
11 A. No, that's not true.	11 ask it again.
12 Q. Did DynaMesh retain its effective porosity?	12 In 2013, Doctor, you state in this study,
13 A. Yes, but Sofradim light as well.	13 "Clinical studies have to prove whether devices with
14 Q. Okay. And at the end of the study in 2007,	14 high porosity, as well as high structural stability,
15 you say that, in the abstract, "Further in vivo	15 can improve the patients' outcome."
16 studies have to investigate whether the preservation	16 There's still no clinical studies that prove
17 of a high effective porosity under stress may help to	17 whether devices with high porosity as well as high
18 improve biocompatibility of textile implants."	18 structural stability can improve the patients'
19 Is that correct?	19 outcome; true?
20 A. Yes.	20 A. There are no comparative clinical studies at
21 Q. And "in vivo studies" means studies in	21 all.
22 animals?	22 Q. Thank you.
23 A. Amongst all, but more or less the most	23 Now, Doctor, in this study in both 2007 and
24 important way to learn what happens to the meshes is	24 in 2013, you identified 1,000 microns or 1 millimeter
Page 123	Page 125
1 the analyses of explanted materials from humans.	1 as the standard of effective porosity in
2 Q. Okay. The study says further in vivo	2 polypropylene; correct?
3 studies. That means studies of mesh in animals;	3 A. Yes, that is what we used.
4 correct? Isn't that what that means?	4 Q. But you used 600 microns for PVDF; correct?
5 A. I guess at that time we thought that -- this	5 A. Yes.
6 was a setting in a lab without any tissue, without	6 Q. Now, it's true in the context of effective
7 any biology, and we said this testing from the lab	7 porosity, if a pore is reduced by even 10 microns, to
8 has to be transferred to the biology, and this --	8 990 microns, it does not get counted in a porosity
9 therefore, we said we need this in vivo studies, and	9 calculation; correct?
10 there's no specification to animal or reduction to	10 A. That is correct.
11 animals.	11 Q. And so it's only pores with 1,000 microns in
12 Q. There have been no in vivo studies to	12 all directions that are included in the effective
13 investigate whether the preservation of a high	13 porosity calculation; correct?
14 effective porosity under stress may help to improve	14 A. That depends on the polymer. If you have
15 biocompatibility of textile implants, has there?	15 another polymer where you know that it behaves a
16 A. Not before, because this was the presentation	16 little bit better, then it is very easy to change the
17 of this -- this conception.	17 machine. It is objective, reproducible, reliable.
18 Q. And in 2013 in Exhibit 0697, you repeat, the	18 So if you, as a manufacturer, have a polymer where
19 clinical studies have to prove whether devices with	19 you know that it is -- critical diameter would be
20 high porosity as well as high structural stability	20 only 900 microns, yeah, then you can make these
21 could improve the patient's outcome. There's still	21 measurements with your critical diameter.
22 no clinical studies that prove wherefore devices with	22 Q. Okay. And the machine --
23 high porosity as well as high structural stability	23 A. Our data, we, up to now -- we just had the
24 can improve the patient's outcome, are there?	24 data of 1,000 for polypropylene and 600 for PVDF,

Page 126	Page 128
<p>1 but -- yeah.</p> <p>2 Q. But you didn't -- those are the only two</p> <p>3 measurements you took, at 1,000 for polypropylene and</p> <p>4 600 for PVDF; correct?</p> <p>5 A. Measurements, there have been a lot, but</p> <p>6 these are the two, yeah. If you applied this</p> <p>7 measurement to this machine for polypropylene, you</p> <p>8 can put in only one range.</p> <p>9 Q. Okay.</p> <p>10 A. One limit.</p> <p>11 Q. You know, other scientists disagree with your</p> <p>12 1,000 figure for polypropylene, don't they?</p> <p>13 A. I'm not aware of anyone who said that the</p> <p>14 pore size and the bridging does not happen, no.</p> <p>15 Q. Okay.</p> <p>16 A. And I don't know any measurements showing</p> <p>17 that it is different.</p> <p>18 MR. ANDERSON: Keep this separate.</p> <p>19 - - -</p> <p>20 (Klinge Trial Exhibit No. 2, Article entitled</p> <p>21 "Synthetic and biodegradable prostheses in pelvic</p> <p>22 floor surgery," Bates stamped DX3036.1 through</p> <p>23 DX3036.11, was marked for identification.)</p> <p>24 - - -</p>	<p>1 A. He used another classification.</p> <p>2 Q. Okay. That's my point. He describes the</p> <p>3 synthetic implant materials for Prolene and Marlex as</p> <p>4 totally microporous; correct?</p> <p>5 A. That is correct.</p> <p>6 Q. And he disagrees with your classification?</p> <p>7 A. No. No. There is no -- not any data showing</p> <p>8 that the bridging doesn't occur. There is not any</p> <p>9 data that 1 millimeter is not a critical limit. The</p> <p>10 only thing that happens is he used the classification</p> <p>11 of Amid, who was produced when we start -- before we</p> <p>12 started our joint collaboration with Ethicon, and at</p> <p>13 that time there hasn't been any large pore mesh. So</p> <p>14 Amid was not able to consider these large pore meshes</p> <p>15 in his classification. So when using this old</p> <p>16 classification, of course, you will have a mix of</p> <p>17 these terms.</p> <p>18 Q. Okay.</p> <p>19 A. But it doesn't -- is relevant in any way to</p> <p>20 the fact that small pores have an increased risk,</p> <p>21 makes it unsafe and are filled by scar tissue.</p> <p>22 Q. Go to the bottom.</p> <p>23 A. So no.</p> <p>24 Q. I'm sorry. Go to the bottom of page 4.</p>
Page 127	Page 129
<p>1 BY MR. THOMAS:</p> <p>2 Q. Let me show you what's been marked as Klinge</p> <p>3 Trial Exhibit Number 2. It's an article by Deprest</p> <p>4 and others.</p> <p>5 A. Yes.</p> <p>6 Q. Are you familiar with this article?</p> <p>7 A. I think a long time ago I read it.</p> <p>8 Q. And this is an article in 2005?</p> <p>9 A. Yes.</p> <p>10 Q. About the same time that you came out with</p> <p>11 your article about 1,000 millimeters; correct?</p> <p>12 A. Obviously.</p> <p>13 Q. And do you know Dr. Deprest?</p> <p>14 A. Yes, very well.</p> <p>15 Q. And he's writing about synthetic and</p> <p>16 biodegradable prostheses in pelvic floor surgery;</p> <p>17 correct?</p> <p>18 A. Obviously, yeah.</p> <p>19 Q. If you turn to page 4 of Klinge Trial</p> <p>20 Deposition Exhibit 2, there's a description of Type I</p> <p>21 meshes. Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. And it includes in Type I meshes, described</p> <p>24 them as totally microporous; correct?</p>	<p>1 A. Yeah.</p> <p>2 Q. And Dr. Deprest says that, "Pore sizes</p> <p>3 greater than 75 microns allow for rapid ingrowth of</p> <p>4 fibroblasts and vascular elements necessary to anchor</p> <p>5 the implant within the native tissue."</p> <p>6 That's what he says, isn't it?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. Is that correct?</p> <p>9 A. The fact is --</p> <p>10 Q. Is it correct?</p> <p>11 MR. ANDERSON: Is what correct?</p> <p>12 BY MR. THOMAS:</p> <p>13 Q. Is that statement correct? Do you agree with</p> <p>14 that?</p> <p>15 A. The statement is only correct if you assume</p> <p>16 that you need a pore size of 75 microns to allow scar</p> <p>17 to get integrated. Our point is that we want to</p> <p>18 separate the integration of fat and scar, and,</p> <p>19 therefore, you need a completely different size of</p> <p>20 the holes. If you are agreed that you want to have</p> <p>21 scar in your implant, then, of course, yeah, this is</p> <p>22 correct.</p> <p>23 Q. So you --</p> <p>24 A. But it's a completely mix-up of the -- and</p>

Page 130	Page 132
<p>1 there is no fact to it. It is a citation of Amid's</p> <p>2 classification and nothing more.</p> <p>3 Q. Okay. You could have changed the settings on</p> <p>4 your effective porosity testing to measure for 75</p> <p>5 microns; correct?</p> <p>6 A. Everyone can do it. Yeah.</p> <p>7 Q. But you didn't do that?</p> <p>8 A. No.</p> <p>9 Q. Let me show you now what's been marked as --</p> <p>10 and, by the way, he was joined in that study by eight</p> <p>11 other people on the study; correct? On the first</p> <p>12 page you can count the people who were involved in</p> <p>13 the study.</p> <p>14 A. Yeah.</p> <p>15 - - -</p> <p>16 (Klinge Trial Deposition Exhibit No. 3,</p> <p>17 Article entitled "The biology behind fascial defects</p> <p>18 and the use of implants in pelvic organ prolapse</p> <p>19 repair," Bates stamped DX30360.1 through DX30360.10,</p> <p>20 was marked for identification.)</p> <p>21 - - -</p> <p>22 BY MR. THOMAS:</p> <p>23 Q. Let me show you now what I have had marked as</p> <p>24 Klinge Trial Exhibit Number 3. And this is a --</p>	<p>1 A. The next sentence.</p> <p>2 Q. Yes. Larger --</p> <p>3 A. "Larger pores limit the fibrosis process to</p> <p>4 perifilament region and the pores get filled with</p> <p>5 fat."</p> <p>6 Q. Right. But you didn't do any testing on your</p> <p>7 effective porosity machine at 400 to 500 microns, did</p> <p>8 you?</p> <p>9 A. We didn't make a calculation exactly with</p> <p>10 this one, no.</p> <p>11 Q. Okay. And do you agree with Dr. Deprest that</p> <p>12 in the use of implants in pelvic organ prolapse</p> <p>13 repair that peak ingrowth is reached at pore size</p> <p>14 around 4- to 500 microns? Do you agree with that?</p> <p>15 A. If you are -- this is while you are coming</p> <p>16 from tissue engineering, and it is not the value that</p> <p>17 helps us to define whether you have fat and scar</p> <p>18 tissue. Therefore, it is no argument against the</p> <p>19 relevance of effective porosity for the clinical</p> <p>20 outcome.</p> <p>21 Q. Okay. But you didn't measure at 4- or 500</p> <p>22 microns, which is the peak level identified by</p> <p>23 Dr. Deprest, did you?</p> <p>24 A. In what -- in what sense should --</p>
Page 131	Page 133
<p>1 another paper a year later by Dr. Deprest; correct?</p> <p>2 A. Yes.</p> <p>3 Q. It's in 2006. This is a year after your</p> <p>4 paper; correct?</p> <p>5 A. Yes.</p> <p>6 Q. And if you'll go to page 3 of this trial</p> <p>7 Exhibit 3, once again, he cites to the Amid</p> <p>8 classification; correct? Down on the right, lower</p> <p>9 right-hand corner?</p> <p>10 A. Yes.</p> <p>11 Q. And you see the classification of implants</p> <p>12 where it talks about macroporous -- that's with an</p> <p>13 a -- that's greater than 75 microns. Do you see</p> <p>14 that?</p> <p>15 A. Yeah.</p> <p>16 Q. And it says in the lower right-hand side</p> <p>17 that, "Pore sizes greater than 75 microns allow for</p> <p>18 rapid ingrowth of fiberglass and vascular elements</p> <p>19 necessary to anchor the implant within the native</p> <p>20 tissue. Peak ingrowth is reached at pore size around</p> <p>21 400 to 500 microns."</p> <p>22 Did I read that correctly?</p> <p>23 A. Yeah.</p> <p>24 Q. You didn't --</p>	<p>1 Q. Yeah. You didn't conduct those tests on --</p> <p>2 A. If --</p> <p>3 Q. -- either DynaMesh or on polypropylene in the</p> <p>4 tests you did with Professor Mühl; correct?</p> <p>5 A. If we place a mesh into this machine and</p> <p>6 defined the critical size of, let's say, 200 microns,</p> <p>7 yeah, there will never be an effective pore -- pore</p> <p>8 that will be filled by fat tissue.</p> <p>9 Q. My --</p> <p>10 A. We know this, yeah.</p> <p>11 Q. My point is, Doctor, you didn't test at the</p> <p>12 areas identified by Dr. Deprest as being the peak</p> <p>13 ingrowth for tissue as cited in the exhibit I just</p> <p>14 gave you. You've not done that, have you? True?</p> <p>15 A. But in the --</p> <p>16 Q. Is it true?</p> <p>17 A. We never modified this testing with these</p> <p>18 data, yes, that is true.</p> <p>19 Q. Okay.</p> <p>20 A. But it doesn't make any sense.</p> <p>21 - - -</p> <p>22 (Defendant's Exhibit No. DX30064, Article</p> <p>23 entitled "Classification of biomaterials and their</p> <p>24 related complications in abdominal wall hernia</p>

Page 134	Page 136
<p>1 surgery," Bates stamped DX30064.1 through DX30064.7, 2 was marked for identification.) 3 - - - 4 BY MR. THOMAS: 5 Q. All right. And you know that there are some 6 people -- let me show you what's been marked as 7 Defendant's Exhibit 30064, and 30064 is the Amid 8 paper from 1997. You recognize that? 9 MR. ANDERSON: I'm sorry, Counsel. Is this 10 going to be a defense exhibit? Because the other 11 ones you used a defense exhibit for Klinge. Do 12 you want it to be a Klinge exhibit? Because 13 you -- 14 MR. THOMAS: I know that. And just for your 15 benefit and my admission, I didn't realize when I 16 marked them that they had numbers on them. All 17 I'm trying to do is not create new numbers if I 18 can. 19 MR. ANDERSON: Okay. 20 MR. THOMAS: And we'll change -- we'll change 21 the numbers at a later time if I have to. 22 MR. ANDERSON: So that it correlates with 23 your exhibit numbers. Okay. That's fine. 24 MR. THOMAS: I'm just trying to identify them</p>	<p>1 Q. It's fair to understand, Doctor, that the two 2 studies that you did with Professor Mühl that we've 3 had marked one as Plaintiff's 0697 and the other as 4 Klinge Trial Exhibit Number 1, are not, standing 5 alone, able to replicate what happens in the human 6 body; correct? 7 A. They are able to replicate some aspects. 8 Q. Okay. But the whole point of these studies 9 is to give people a starting point so that you can 10 use this information to develop a better model to 11 understand what happens in the human body; correct? 12 A. It helps to predict the risk for rigid 13 fibrosis without any forces and what happens to your 14 textile, to your device when you applied some forces. 15 Therefore, it gives a measure so that you can 16 optimize the design of the meshes, yeah. 17 Q. Uniaxial forces only; correct? 18 A. Uniaxial forces, yeah. And you can modify 19 the forces. You can modify the diameter depending on 20 the polymer you are using. So a very standardized 21 technique, open for everyone. 22 Q. And so when you go back to Plaintiff's 0697 23 and you go to page 5 -- 24 MR. ANDERSON: Hold on. Let's get 06 --</p>
Page 135	Page 137
<p>1 as best I can. 2 MR. ANDERSON: Yeah. 3 BY MR. THOMAS: 4 Q. Now, Doctor, I've shown you Defendant's 5 Exhibit 30064, and this is the Amid paper that we 6 have been talking about, isn't it? 7 A. Yes. 8 Q. And this is what has been known as the Amid 9 classifications since 1997; correct? 10 A. Yes. 11 Q. And you know that there's some people that 12 still follow the Amid classification; correct? 13 A. I personally will follow it when -- when 14 looking at the risk for infection and material 15 infection, I -- it's still proper to follow this 16 classification. If you want to separate the bridging 17 fibrosis, the scarring of the pores, it is not 18 appropriate. 19 Q. But that's you. You know that there are some 20 scientists who still follow the Amid class at this 21 indication? 22 A. Depends on the purpose why. 23 Q. Okay. Thank you. 24 A. What do you want to have with the -- yeah.</p>	<p>1 that's not it. 2 MR. THOMAS: It's the 2013 study. 3 MR. ANDERSON: Yeah. But I moved stuff. 4 Here. 5 THE WITNESS: Five. 6 BY MR. THOMAS: 7 Q. Are you there? The porosity of the 8 Gynemesh PS and the Gynemesh -- and the DynaMesh, I'm 9 sorry, are measured, on the very top of that article. 10 Do you see that? 11 A. Where are you? 12 Q. Is that textile porosity where it says 13 porosity at percentage? 14 A. I guess it's the textile porosity. 15 Q. Okay. Do you know what it is? 16 A. The textile porosity is the area that is not 17 covered by the ligaments. 18 Q. Okay. 19 A. So maybe this is the easiest definition of 20 this one. 21 Q. Do you know under Gynemesh where it's 62.9, 22 do you know what that represents? 23 A. Where you are? 24 Q. Under porosity at the top in the figure, in</p>

Page 138	Page 140
<p>1 Figure 3 on the far left. Doctor -- Doctor, if you</p> <p>2 look at page 5 --</p> <p>3 A. Yeah.</p> <p>4 Q. -- of Exhibit 0697, I'm looking at</p> <p>5 Gynemesh PS with no force, zero newtons per</p> <p>6 centimeter, under arm 1, and there's a figure 62.9.</p> <p>7 A. Yeah.</p> <p>8 Q. What does that mean?</p> <p>9 A. That means when you made an image, that 67 --</p> <p>10 62.9 percent of this area is not covered by</p> <p>11 filaments.</p> <p>12 Q. Okay. And that's arm 1; correct?</p> <p>13 A. That's arm 1.</p> <p>14 Q. And then arm 3 is 60.1; correct?</p> <p>15 A. Yeah.</p> <p>16 Q. And if you compare that with DynaMesh arm 1,</p> <p>17 that is equal to or greater than the value for</p> <p>18 DynaMesh; correct?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. Now, you agree that biocompatibility</p> <p>21 of long-term implantable devices can be defined as</p> <p>22 the ability of the device to perform its intended</p> <p>23 function with the desired degree of incorporation in</p> <p>24 the host without eliciting any undesirable, local or</p>	<p>1 Q. Okay.</p> <p>2 A. There's no way.</p> <p>3 Q. So the answer is there are no studies?</p> <p>4 A. There are no studies proving the safety or</p> <p>5 the superiority of any of these devices.</p> <p>6 Q. Now, Doctor, when we talked about in vivo</p> <p>7 studies, we're talking about studies conducted in</p> <p>8 animals; correct?</p> <p>9 A. It's one part, yeah.</p> <p>10 Q. And you used rats in studies to help</p> <p>11 determine types of inflammatory reactions which occur</p> <p>12 with implanted meshes, haven't you?</p> <p>13 A. In this collaboration that we started</p> <p>14 together with Ethicon, we used rats, rabbits and</p> <p>15 other animals. So depending on the specific</p> <p>16 question, we need different models.</p> <p>17 Q. And the reason why you did that was so that</p> <p>18 you could place mesh in animals and study the tissue</p> <p>19 response to that mesh; correct?</p> <p>20 A. Yes.</p> <p>21 Q. And you also used rats in studies to</p> <p>22 determine the extent to which mesh integrates into</p> <p>23 the tissues of the rat?</p> <p>24 A. As I told you, we use rats, rabbits, but we</p>
<p style="text-align: center;">Page 139</p> <p>1 systematic effects in the host?</p> <p>2 A. Yes.</p> <p>3 Q. And you know of no studies -- strike that.</p> <p>4 You agree that Prolene Soft Mesh has a better</p> <p>5 biocompatibility than the Prolene mesh used in hernia</p> <p>6 repair?</p> <p>7 A. It depends on the specific design and -- of</p> <p>8 the different -- it depends from the location and --</p> <p>9 Q. Do you have an opinion --</p> <p>10 A. -- to place it.</p> <p>11 Q. Do you have an opinion about whether Prolene</p> <p>12 Soft Mesh has a better biocompatibility than Prolene?</p> <p>13 A. I cannot answer it. I have an opinion, but</p> <p>14 it cannot be answered just by yes or no.</p> <p>15 Q. Okay.</p> <p>16 MR. ANDERSON: I have the same objection.</p> <p>17 Outside the scope of direct.</p> <p>18 BY MR. THOMAS:</p> <p>19 Q. And you know of no studies in a randomized</p> <p>20 controlled trial which compare the biocompatibility</p> <p>21 of Prolene Soft Mesh with another mesh; correct?</p> <p>22 A. There is no way to make a clinical trial</p> <p>23 where this question with sufficient statistical</p> <p>24 power.</p>	<p style="text-align: center;">Page 141</p> <p>1 confirmed all these results by looking at the human</p> <p>2 explants.</p> <p>3 Q. And the reason why you wanted to -- strike</p> <p>4 that.</p> <p>5 You used rats in studies to determine the</p> <p>6 extent to which the mesh implanted into the rat</p> <p>7 integrates into the tissues; correct?</p> <p>8 A. I didn't get the entire question.</p> <p>9 Q. Let me ask it again.</p> <p>10 In your experience, you use rats in studies</p> <p>11 to determine the extent to which the mesh implanted</p> <p>12 in the rats integrates into the tissues of the rats;</p> <p>13 correct?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. And you know that Ethicon has</p> <p>16 conducted tissue reaction and tissue integration</p> <p>17 studies where Ethicon implanted mesh in animals,</p> <p>18 don't you?</p> <p>19 A. Yes, I know.</p> <p>20 Q. And you have reviewed some of those studies;</p> <p>21 correct?</p> <p>22 A. Yes.</p> <p>23 - - -</p> <p>24 (Klinge Trial Exhibit No. 4, Ethicon Final</p>

Page 142	Page 144
<p>1 Report, PSE Accession No. 00-0035, An Exploratory</p> <p>2 91-day Tissue Reaction Study of Polypropylene-based</p> <p>3 Surgical Mesh in Rats (PSE ACC. NO. 00-0035), was</p> <p>4 marked for identification.)</p> <p>5 - - -</p> <p>6 BY MR. THOMAS:</p> <p>7 Q. I'm going to show you what I have marked as</p> <p>8 Klinge Trial Exhibit Number 4.</p> <p>9 Dr. Klinge, Klinge Trial Exhibit Number 4 is</p> <p>10 a document titled -- document dated July 11, 2001.</p> <p>11 It's a final report, and it's titled, "An Exploratory</p> <p>12 91-Day Tissue Reaction Study of Polypropylene-Based</p> <p>13 Surgical Mesh in Rats."</p> <p>14 You've seen that before, haven't you?</p> <p>15 A. I think I saw it, yeah.</p> <p>16 Q. And you reviewed that in connection with your</p> <p>17 work in this litigation, didn't you?</p> <p>18 A. Yes.</p> <p>19 Q. And you did not see this study before this</p> <p>20 litigation; correct?</p> <p>21 A. That is correct.</p> <p>22 Q. And Ethicon conducted this study in the</p> <p>23 period 2000 to 2001; correct?</p> <p>24 A. It should be correct.</p>	<p>1 into the mesh; correct?</p> <p>2 A. You have to define it very carefully what --</p> <p>3 what type of tissue, what are -- which cells you are</p> <p>4 looking at, what happens in the pores, which is your</p> <p>5 area of interest. So research is not so simple just</p> <p>6 to say we are making it and looking to this, no.</p> <p>7 Q. Okay.</p> <p>8 A. It is --</p> <p>9 Q. You understood that this study placed mesh</p> <p>10 under the skin of rats --</p> <p>11 A. Yeah.</p> <p>12 Q. -- in order to look at the tissue reaction to</p> <p>13 that mesh as well as to analyze the extent to which</p> <p>14 the tissue integrated into the mesh. You understand</p> <p>15 that was a goal of this study?</p> <p>16 A. Yeah. We did it several time ourselves</p> <p>17 but --</p> <p>18 Q. Same type --</p> <p>19 A. -- we know the limitations of this very, very</p> <p>20 well.</p> <p>21 Q. I understand. But you've done this same type</p> <p>22 of study yourself with different animals and</p> <p>23 different meshes?</p> <p>24 A. And for some other purposes with this</p>
<p style="text-align: center;">Page 143</p> <p>1 Q. And let's go to page 2 of 27 of this study.</p> <p>2 A. Two of 27.</p> <p>3 Q. See under "Summary"? Right there under</p> <p>4 "Summary."</p> <p>5 The first line, "A subcutaneous implantation</p> <p>6 study was conducted to assess the tissue reaction</p> <p>7 profile and qualitative integration of several</p> <p>8 different constructions of polypropylene surgical</p> <p>9 meshes."</p> <p>10 Tell the jury what a subcutaneous</p> <p>11 implantation study is.</p> <p>12 A. A subcutaneous implantation study, then you</p> <p>13 usually place small pieces of a mesh in the</p> <p>14 subcutaneous area beneath -- underneath the skin on</p> <p>15 top of the muscles, so it's laying in fat. It can be</p> <p>16 done very easily. And, yeah, and then you are able,</p> <p>17 then, after some time that you can explant the</p> <p>18 material and look to the tissue reaction to this.</p> <p>19 Q. Okay. And you can look to both the tissue</p> <p>20 reaction, which is the -- how the body reacts to the</p> <p>21 mesh; correct?</p> <p>22 A. Yes.</p> <p>23 Q. And the qualitative integration of the mesh.</p> <p>24 That means the extent to which the tissue integrates</p>	<p style="text-align: center;">Page 145</p> <p>1 specific hypothesis, yeah.</p> <p>2 Q. Okay. And if you turn the page, please, it</p> <p>3 talks about materials. Do you see that?</p> <p>4 A. There we are.</p> <p>5 Q. We're on page 3 of 27 --</p> <p>6 A. Yeah.</p> <p>7 Q. -- of Klinge Trial Exhibit Number 4.</p> <p>8 A. Uh-huh. Bard, Surgipro, Prolene and Prolene</p> <p>9 Soft, Vypro.</p> <p>10 Q. And there are listed there seven different</p> <p>11 meshes that are tested; correct?</p> <p>12 A. Yes.</p> <p>13 Q. And the Bard mesh that's tested there is a</p> <p>14 competitor's mesh, isn't it? Bard mesh is not made</p> <p>15 by Ethicon?</p> <p>16 A. No, no, no.</p> <p>17 Q. Excuse me. Bard mesh is not made by Ethicon;</p> <p>18 correct?</p> <p>19 A. That is correct.</p> <p>20 Q. Thank you.</p> <p>21 And that's what you referred to as a small</p> <p>22 pore heavyweight mesh; correct?</p> <p>23 A. Yes.</p> <p>24 Q. Surgipro mesh, likewise, is a mesh</p>

Page 146	Page 148
<p>1 manufactured by a competitor; correct?</p> <p>2 A. Yes.</p> <p>3 Q. Now, Prolene mesh is a -- is the hernia mesh</p> <p>4 used by Ethicon that has a pore size smaller than the</p> <p>5 Prolift mesh; correct?</p> <p>6 A. How -- what is your definition of the pore</p> <p>7 size and how it is measured? What is the pore size</p> <p>8 of the Prolift mesh? So it is insufficient. We know</p> <p>9 it meanwhile to give just one figure.</p> <p>10 Q. Without tension it is clear that the pore</p> <p>11 size of the Prolene mesh used in hernia repair is</p> <p>12 smaller than the --</p> <p>13 A. The area of affected pores maybe.</p> <p>14 Q. Let me ask the question again, and let me</p> <p>15 finish it before you give an answer.</p> <p>16 A. Sorry.</p> <p>17 Q. Doctor, it's true that the area of the pore</p> <p>18 for the Prolene mesh used in hernia repair is smaller</p> <p>19 than the pore size without tension of the pore size</p> <p>20 of the Prolene polypropylene mesh used in Prolift?</p> <p>21 MR. ANDERSON: Objection.</p> <p>22 THE WITNESS: Again, it would be necessary to</p> <p>23 make a testing of the effective porosity for the</p> <p>24 Prolene mesh. I didn't do it, so I know -- I</p>	<p>1 Soft Mesh; correct?</p> <p>2 A. Yes.</p> <p>3 Q. And the company tested Vypro mesh. You see</p> <p>4 that?</p> <p>5 A. Yes.</p> <p>6 Q. And it tested three different kinds of Vypro</p> <p>7 mesh. Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. And Vypro mesh is the mesh that you helped</p> <p>10 Ethicon develop; correct?</p> <p>11 A. Yes.</p> <p>12 Q. And Vypro mesh is the mesh that you</p> <p>13 characterize as being lightweight large pore;</p> <p>14 correct?</p> <p>15 A. Yes.</p> <p>16 Q. And the company in Klinge Trial Exhibit</p> <p>17 Number 4 compared the tissue reaction and tissue</p> <p>18 integration of all seven of these meshes; correct?</p> <p>19 A. Yeah.</p> <p>20 Q. And they implanted these meshes in rats for</p> <p>21 7 days, 28 days, 63 days, and 91 days; correct?</p> <p>22 A. Yeah, that is correct.</p> <p>23 Q. And after each of these time frames, some of</p> <p>24 the rats were killed, sacrificed, and then the mesh</p>
Page 147	Page 149
<p>1 don't know it.</p> <p>2 BY MR. THOMAS:</p> <p>3 Q. I'm not talking about effective porosity.</p> <p>4 I'm not -- I'm talking about porosity at rest without</p> <p>5 tension.</p> <p>6 A. The textile porosity --</p> <p>7 Q. Yes.</p> <p>8 A. -- you mean.</p> <p>9 Q. Well, if you want to call it textile</p> <p>10 porosity, that's fine.</p> <p>11 A. But this is essential, because we are</p> <p>12 sticking to the effective porosity. We wanted to</p> <p>13 know what happens to the tissue. The textile</p> <p>14 porosity is not relevant, so --</p> <p>15 Q. Okay. To you.</p> <p>16 A. There are no figures about this.</p> <p>17 Q. Okay. The company used, in its study,</p> <p>18 Prolene mesh, which is the same mesh used in hernia</p> <p>19 repair. You agree with that?</p> <p>20 A. There has been a Prolene mesh used in hernia</p> <p>21 repair, though there are some modifications. It is</p> <p>22 not clear which modification exactly was used here,</p> <p>23 but, yeah.</p> <p>24 Q. Okay. And the company also tested Prolene</p>	<p>1 removed so it could be analyzed; correct?</p> <p>2 A. Yeah.</p> <p>3 Q. And when you removed the mesh from the animal</p> <p>4 to be analyzed, how do you prepare samples? What's</p> <p>5 the proper way to prepare samples?</p> <p>6 A. Usually the tissue sample is fixed in</p> <p>7 formaldehyde, and then later on it is -- it is put</p> <p>8 into a paraffin so that you can make some sections of</p> <p>9 it, and then later on it's stained.</p> <p>10 Q. And so the formaldehyde is added to the</p> <p>11 samples upon withdrawal not only as a preservative</p> <p>12 but to fix the tissue in place; correct?</p> <p>13 A. To stop the degradation of the tissues. If</p> <p>14 you don't use formaldehyde and you're storing some</p> <p>15 tissue at home, you will see a catastrophe. It will</p> <p>16 be destroyed within some few days.</p> <p>17 Q. And after the mesh is then cut into slides</p> <p>18 from the paraffin, a study pathologist looked at</p> <p>19 these slides; correct?</p> <p>20 A. Someone is looking sometime, yeah.</p> <p>21 Q. Well, you know that a pathologist in this</p> <p>22 case looked at the slides. Do you know that?</p> <p>23 A. In this case, yeah. But it's not necessary</p> <p>24 that it has to be a pathologist.</p>

Page 150	Page 152
<p>1 Q. But a pathologist is what? What's a 2 person -- what's a pathologist do?</p> <p>3 A. A pathologist is someone who has the training 4 to investigate tissues that are extracted by some 5 surgical means or from some tissues, and there he was 6 trained to identify the changes in these tissues.</p> <p>7 Q. Now, you didn't work at the institute of 8 pathology at your hospital, did you?</p> <p>9 A. No.</p> <p>10 Q. And you don't -- you didn't do a residence in 11 pathology, did you?</p> <p>12 A. No.</p> <p>13 Q. And you had no fellowship in pathology, did 14 you?</p> <p>15 A. No.</p> <p>16 Q. As a matter of fact, you're not permitted to 17 sign pathology reports at your hospital; correct?</p> <p>18 A. That is correct.</p> <p>19 Q. Now --</p> <p>20 A. But in research, the examination never is 21 done by the pathologist but by the researcher 22 themselves.</p> <p>23 MR. THOMAS: Object. Move to strike 24 everything after "that's correct."</p>	<p>1 put under a microscope; correct?</p> <p>2 A. Yeah.</p> <p>3 Q. And it's the microscopic observation by the 4 person looking at it that causes him to reach the 5 conclusions that they express in the report; correct?</p> <p>6 A. No, not always. You have to look to the 7 microscopical appearance of the explants as well. So 8 the microscopical mainly is an explanation of what 9 happens, but for the patient it's more important what 10 happens clinically.</p> <p>11 Q. You've never looked at the slides that this 12 study generated in Klinge Trial Exhibit Number 4, 13 have you?</p> <p>14 A. I never got the slides from this study from 15 study from Barbolt. I've seen it.</p> <p>16 Q. And you know they're still available, don't 17 you?</p> <p>18 A. What?</p> <p>19 Q. You know they're still available, don't you?</p> <p>20 A. They are still available?</p> <p>21 Q. Yes. You haven't looked at it?</p> <p>22 A. I didn't get it, yes.</p> <p>23 THE WITNESS: Is it possible to get?</p> <p>24 BY MR. THOMAS:</p>
Page 151	Page 153
<p>1 BY MR. THOMAS:</p> <p>2 Q. Let's go to page 2. And page 2, the third 3 line down under "Summary," the summary finds, "The 4 inflammatory reaction among the different 5 constructions was relatively similar, ranging from 6 minimal to mild in intensity and, thus, were all 7 considered to be biocompatible."</p> <p>8 Did I read that correctly?</p> <p>9 A. Yes.</p> <p>10 Q. If you go to page 9, first line of the second 11 paragraph on page 9, page 9 of 27 up at the top. 12 "Study found that all of the meshes had sufficient 13 porosity to allow for integration with surrounding 14 connective tissue."</p> <p>15 Did I read that correctly?</p> <p>16 A. Yes.</p> <p>17 Q. And, Doctor, when people conduct studies, 18 they make these slides that you referred to with the 19 tissue samples; correct? So that they can be looked 20 at under a microscope, that's what you do; correct?</p> <p>21 A. Again?</p> <p>22 Q. When studies, like Klinge Trial Exhibit 23 Number 4, conducted the tissue that's removed from 24 the slices, the paraffin, it's made into slides to</p>	<p>1 Q. Let's go to Plaintiff's Exhibit 271. That's 2 your 2005 paper.</p> <p>3 MR. ANDERSON: That's not it.</p> <p>4 BY MR. THOMAS:</p> <p>5 Q. And this is a paper that you prepared with 6 Dr. Klosterhalfen and Dr. Junge?</p> <p>7 A. That is correct.</p> <p>8 Q. And would you call this a review article?</p> <p>9 A. Yes.</p> <p>10 Q. And you're kind of reviewing the state of 11 medicine and science on the concept of lightweight 12 and large pore mesh for hernia repair in this paper; 13 correct?</p> <p>14 A. Please can you repeat the question, the 15 details?</p> <p>16 MR. THOMAS: Can you read that back, please.</p> <p>17 THE COURT REPORTER: "And you're kind of 18 reviewing the state of medicine and science on 19 the concept of lightweight and large pore mesh 20 for hernia repair in this paper; correct?"</p> <p>21 THE WITNESS: And "you're kind"?</p> <p>22 MR. THOMAS: I'm sorry.</p> <p>23 THE WITNESS: I don't understand the first 24 words.</p>

Page 154	Page 156
1 MR. THOMAS: That's my fault. I apologize.	1 MR. ANDERSON: Yeah. But your version is
2 BY MR. THOMAS:	2 different from this version because you've got
3 Q. The purpose of this article,	3 yours stamped at the bottom.
4 Plaintiff's 2071, is to review the state of science	4 THE WITNESS: Do you have the pages?
5 and medicine on the mesh concept known as lightweight	5 MR. ANDERSON: And we don't have the stamped.
6 and large porous for hernia repair?	6 THE WITNESS: We don't have the same pages.
7 A. Yes, that is --	7 MR. THOMAS: I'll do it from your document.
8 Q. Thank you.	8 Let me see if I can find the page. I wonder why
9 A. -- true.	9 it's different.
10 Q. And in here you talk not only about old	10 BY MR. THOMAS:
11 meshes but also new meshes; correct?	11 Q. Let's go to page 10 of Exhibit 0271, please.
12 A. The new generation mesh, yeah.	12 Do you have page 10?
13 Q. And in the abstract, which is on the first	13 A. Yes.
14 page of 2071, you state that: "All experimental	14 Q. On page 10 you and your coauthors begin
15 evidence and first clinical data indicate the	15 talking about the new generation of lightweight large
16 superiority of the lightweight large porous mesh	16 porous meshes, Vypro and Vypro II; correct?
17 concept with regard to a reduced number of long-term	17 A. Yes.
18 complications and particularly increased comfort and	18 Q. And is the purpose of this discussion to talk
19 quality of life after hernia repair."	19 about the promise of Vypro and Vypro II in hernia
20 Correct?	20 repair; correct?
21 A. That is correct.	21 A. The purpose of what?
22 Q. And what you're referring to there are your	22 Q. The promise.
23 initial results; correct?	23 A. Promise?
24 A. What is your definition of "initial"?	24 Q. The future potential benefits of Vypro -- let
Page 155	Page 157
1 Q. Well, there's certainly --	1 me ask the question again.
2 A. It is what we know to this time point.	2 On page 10 of Exhibit 0271, there is a
3 Q. There are no long-term studies available to	3 paragraph titled "The New Generation: Lightweight
4 determine the extent to which lightweight large pore	4 Large Porous Meshes." Correct?
5 mesh behaves better than small pore heavyweight mesh,	5 A. Yes.
6 as you've described them in this study, at the time	6 Q. And in that paragraph, series of paragraphs,
7 that you published this study?	7 you discuss Vypro and Vypro II?
8 A. At this time, no, not to my knowledge.	8 A. Yes.
9 Q. Okay. Let's go to page 112, please.	9 Q. And those -- Vypro I is the mesh that you
10 I don't think that's the right page, Doctor.	10 helped develop with Ethicon for hernia repair;
11 112.	11 correct?
12 MR. ANDERSON: 112?	12 A. Yes.
13 MR. THOMAS: Under --	13 Q. And Vypro II was a subsequent development of
14 MR. ANDERSON: You're reading off of your	14 Vypro again in hernia repair; correct?
15 exhibit number, but you said go to Plaintiff's	15 A. Yes.
16 Exhibit, so ours doesn't have your -- do you have	16 Q. And the bottom of that paragraph or that
17 your trial exhibit number?	17 section says that, "First clinical trials confirm the
18 MR. THOMAS: I'm looking at this number right	18 expected superiority of the lightweight large porous
19 here, 112. Is that different than yours?	19 mesh concept concerning quality of life after hernia
20 MR. ANDERSON: Yeah. Maybe yours is	20 repairs."
21 different. Let's see. Did you -- did you give	21 What does "quality of life after hernia
22 me your exhibit?	22 repair" mean?
23 MR. THOMAS: You already -- it's already in	23 A. It depends from the -- from the trial that
24 the record, so I didn't.	24 you are doing. Quality of life -- to measure quality

Page 158	Page 160
<p>1 of life, there are different tools depending on the 2 investigator. It can be looking to foreign body 3 sensation. It can be looking to pain. It can be 4 looking to serious complications. So a lot of these 5 things. And there are some attempts to quantify 6 them. There are some questionnaires, as SF-36, which 7 gives a lot of data. So you try to quantify quality 8 of life to know what happens to the patient.</p> <p>9 Q. Okay. And is the quality of life an 10 appropriate end point for a study to determine 11 whether a mesh implanted in the body is functioning 12 appropriately?</p> <p>13 A. It's usually a secondary end point. It's --</p> <p>14 Q. Secondary to recurrence?</p> <p>15 A. Yes.</p> <p>16 Q. Okay.</p> <p>17 A. Usually.</p> <p>18 Q. All right. But it's an important end point 19 to understand how a patient's quality of life has 20 been affected by the hernia repair; correct?</p> <p>21 A. It's one way to measure this.</p> <p>22 Q. And at this time there are no long-term 23 studies on Vypro and Vypro II to determine the 24 quality of life for these patients after hernia</p>	<p>1 it is not possible at all to do this confirmation at 2 clinical studies.</p> <p>3 Q. At the time that you published Exhibit 2075, 4 there were no clinical trials available to confirm 5 the promising preclinical results of the lightweight 6 large porous polypropylene mesh that most 7 manufacturers have added; correct?</p> <p>8 A. So it is correct --</p> <p>9 Q. Thank you.</p> <p>10 A. -- in regard to comparing studies.</p> <p>11 Q. Okay.</p> <p>12 A. It is not correct in regards to the analysis 13 of explants.</p> <p>14 MR. THOMAS: All right. Move to strike 15 everything after "it's correct."</p> <p>16 BY MR. THOMAS:</p> <p>17 Q. You also discuss on page 11 of Exhibit 0271 18 Ultrapro; correct?</p> <p>19 A. Yes.</p> <p>20 Q. And Ultrapro is the mesh that you understand 21 to be the predominant mesh used in hernia repair in 22 Germany; is that correct?</p> <p>23 A. So far I know, yes.</p> <p>24 Q. And at the end of your discussion of</p>
Page 159	Page 161
<p>1 repair; true?</p> <p>2 A. So far I remember the long term is there one, 3 two years maybe. I don't know exactly the Brinkman 4 study when it came up, when it was published there. 5 It was about three years, so it depends from what you 6 are thinking of long term.</p> <p>7 Q. And under polypropylene, next paragraph down, 8 you say, "Most manufacturers have added to their 9 range of polypropylene heavyweight mesh small porous 10 mesh modifications, lightweight large porous 11 adaptation."</p> <p>12 Correct? Did I read that correctly?</p> <p>13 A. Yeah. Yes.</p> <p>14 Q. And if you go to the last sentence in that 15 section it says, "However, clinical trials have yet 16 to confirm the promising preclinical results."</p> <p>17 Now, what does that mean?</p> <p>18 A. That means that at that time we hoped that it 19 is possible to make the clinical trial and to 20 demonstrate that one material is superior to another 21 just by operating 150 patients in this direction 22 or -- and 150 patients with another mesh, and we did 23 some prospective clinical trials with Ethicon 24 together to get this information; but we learned that</p>	<p>1 Ultrapro, you say, "Overall the Monocryl 2 polypropylene composite Ultrapro is currently the 3 member of the lightweight large porous mesh family 4 with the lowest foreign body reaction and optimized 5 handling. The first clinical studies produced 6 encouraging results to move forward with this mesh 7 concept."</p> <p>8 Correct?</p> <p>9 A. Yes.</p> <p>10 Q. And I believe you've already told me that you 11 do not think that Ultrapro -- strike that.</p> <p>12 Ultrapro is the same mesh as Prolift+M; 13 correct?</p> <p>14 A. Prolift+M used the Ultrapro.</p> <p>15 Q. Okay. And you do not believe that Ultrapro, 16 known as Prolift+M, is appropriate for use in the 17 pelvic floor; correct?</p> <p>18 A. This work is focused on the tension-free 19 situation in the abdominal wall without applying any 20 forces to it. At that time we didn't think that 21 someone is using this mesh for a situation where you 22 applied some forces; and, therefore, Ultrapro is 23 still the mesh I think with the largest pores and, 24 therefore, with a pretty nice tissue integration if</p>

Page 162	Page 164
<p>1 applied without any force and tension and if it's 2 laying flat. 3 Q. Is it your opinion that Ultrapro should not 4 be used for abdominal hernia repair? 5 A. For abdominal hernia repair there is, of 6 course, an indication to use it. 7 Q. Okay. And so is it your opinion that 8 Ultrapro is appropriate for abdominal hernia repair, 9 but the same mesh in Ultrapro, which is in Prolift+M, 10 is not appropriate in the pelvic floor? 11 A. It doesn't matter in what tissue you are 12 using it. It is -- you should use it in a 13 tension-free way so that it's laying as an area, as a 14 flat mesh there. If you apply some tension -- and we 15 made ourselves experiments using the Ultrapro close 16 to the diaphragma where we applied some tension to it 17 and got disappointing results with the Ultrapro. So 18 it depends on the specific indication function of 19 these devices. 20 Q. And surgical technique? 21 A. If you are free -- if you are free, of 22 course, with the surgical technique you can do every 23 complication that is imaginable, but there are some 24 procedures that need some forces, and in these cases</p>	<p>1 Q. You answered my question no, so I need to 2 answer it again -- ask it again. 3 It's true that you have never designed a mesh 4 for the treatment of pelvic organ prolapse; true? 5 A. I was involved in the design process in 6 regards to the question whether the textile design 7 fulfills these requirements, but, of course, I'm not 8 entirely manufacturing or designing meshes for the 9 pelvic floor. 10 Q. And can you identify for me any mesh 11 available in the United States today that is -- where 12 the benefits outweigh the risk for the treatment of 13 pelvic organ prolapse? 14 A. You cannot answer this question because it's 15 a general statement. It doesn't make any sense. 16 Q. Okay. Since the work that you've done -- 17 strike that. 18 Since your 2005 article that you've just 19 described, there have been long-term studies 20 comparing lightweight large pore mesh against small 21 pore heavyweight mesh, haven't there? 22 A. There has been published several studies, 23 yeah. 24 - - -</p>
<p style="text-align: center;">Page 163</p> <p>1 this mesh is not a good alternative. It's not a safe 2 alternative. 3 Q. And when you speak about "this mesh," you're 4 talking about Ultrapro? 5 A. Ultrapro. 6 Q. Okay. 7 A. Yeah, you talk. 8 Q. Is there any mesh that you've identified 9 that's appropriate for use in the pelvic floor for 10 the repair of pelvic organ prolapse? 11 A. I cannot give a general statement to this. I 12 know that there are textile constructions and design 13 for meshes that are more resistant to the collapse, 14 but it depends on the indication of the specific 15 situation. There is never one device for all 16 diseases in the pelvic floor. No, it's not done. It 17 has to be very carefully designed for the specific 18 purpose. 19 Q. And you've not designed a specific mesh for 20 the treatment of pelvic organ prolapse; true? 21 A. No. I'm only asked sometimes whether this 22 fits our -- whether the device of the FEG, where I am 23 a consultant, fits to these principles of less 24 material, large pores and stability of the structure.</p>	<p style="text-align: center;">Page 165</p> <p>1 (Klinge Trial Deposition Exhibit No. 5, 2 Article entitled "Long-term outcome and quality of 3 life after open incisional hernia repair - light 4 versus heavyweight meshes", was marked for 5 identification.) 6 - - - 7 BY MR. THOMAS: 8 Q. Let me show you what's been marked as Klinge 9 Trial Exhibit Number 5. It's a research article 10 titled "Long-Term Outcome and Quality of Life After 11 Open Incisional Hernia Repair, Light Versus 12 Heavyweight Meshes." First author is Ladurner. Have 13 you seen this study? 14 A. I guess I have seen it, yeah. 15 Q. And this is a long-term study of up to 72 16 months after incisional hernia repair with 17 lightweight meshes compared to heavyweight meshes; 18 correct? 19 A. Yeah. 20 Q. And the heavyweight mesh is a Prolene mesh. 21 The lightweight mesh is your Vypro mesh; correct? 22 A. Yes. 23 Q. And the two groups were equal in body mass 24 index, age, gender and hernia size; correct?</p>

Page 166	Page 168
<p>1 Is that correct?</p> <p>2 A. Age and gender you said?</p> <p>3 Q. If you look in the abstract, see in the</p> <p>4 abstract?</p> <p>5 A. Yeah.</p> <p>6 Q. It says right in the middle under "Methods,"</p> <p>7 "The two groups were equal in BMI," which is body</p> <p>8 mass index, "age, gender and hernia size." Correct?</p> <p>9 A. Yeah. I'm looking to the data there, so</p> <p>10 hernia size almost -- it's -- yeah.</p> <p>11 Q. Okay. And it finds in the conclusions, "In</p> <p>12 this study the health-related quality of life based</p> <p>13 upon FS36 survey after open incisional hernia repair</p> <p>14 with light or heavyweight meshes is not related to</p> <p>15 the mesh type in the long-term follow-up."</p> <p>16 Did I read that correctly?</p> <p>17 A. You read this correctly.</p> <p>18 Q. And what that means is that the kind of mesh</p> <p>19 that was used in the hernia repair did not affect the</p> <p>20 long-term quality of life in the patients in this</p> <p>21 study; true?</p> <p>22 A. No. Because it is ridiculous to take this</p> <p>23 study with 12 patients in one group and 12 patients</p> <p>24 in the other and to make a read out with the FS36.</p>	<p>1 this conclusion; and it is not justified. And the</p> <p>2 statistical power is just one measure. Yeah, you</p> <p>3 have to consider this. It's not because I want to</p> <p>4 have it. --</p> <p>5 Q. Let's --</p> <p>6 A. And, therefore, it is so difficult to make a</p> <p>7 clinical trial comparing two different devices in</p> <p>8 similar patients.</p> <p>9 Q. Let's --</p> <p>10 A. And, therefore, we need as an alternative</p> <p>11 registry. Yes, I'm sure.</p> <p>12 Q. Registries is the better way to go?</p> <p>13 A. It offers the option to accumulate data from</p> <p>14 a long -- of very many patients over a long period,</p> <p>15 and, of course, the data of the registries over the</p> <p>16 time will help us to understand it.</p> <p>17 MR. THOMAS: Let's take a break and change</p> <p>18 the tape.</p> <p>19 THE VIDEOGRAPHER: We are off the record.</p> <p>20 The time is 12:21 p.m.</p> <p>21 (A recess was taken from 12:21 p.m. until 12:33 p.m.)</p> <p>22 THE VIDEOGRAPHER: This marks beginning of</p> <p>23 Video Number 3. We are back on the record. The</p> <p>24 time is 12:33 p.m.</p>
<p style="text-align: center;">Page 167</p> <p>1 It is so tremendously underpowered that this</p> <p>2 statement, of course, is not confirmed by these data.</p> <p>3 It's ridiculous to discuss this.</p> <p>4 Q. Well, it's certainly what this study reports;</p> <p>5 correct?</p> <p>6 A. You read it correctly.</p> <p>7 Q. Okay. And it's published in the</p> <p>8 peer-reviewed literature?</p> <p>9 A. Yes. Maybe -- yeah. BMC should be peer</p> <p>10 reviewed, yes.</p> <p>11 Q. Okay. But you disagree with the findings in</p> <p>12 Exhibit Number 5; correct?</p> <p>13 A. No. The findings they describe, but the</p> <p>14 conclusion, it is underpowered. You cannot state</p> <p>15 this. So the findings, when they measured it, yeah,</p> <p>16 it can be correct. But to take 12 patients in one</p> <p>17 group and 12 in the other and come up with this</p> <p>18 conclusion, it is dangerous to do so.</p> <p>19 Q. And the reason why is because you want to</p> <p>20 have more subjects in the study or perhaps even a</p> <p>21 registry to allow you to have more data upon which to</p> <p>22 make certain findings; correct?</p> <p>23 A. The reason is coming from the statistics,</p> <p>24 that you need a certain amount of data to come with</p>	<p style="text-align: center;">Page 169</p> <p>1 BY MR. THOMAS:</p> <p>2 Q. Doctor, before we were -- broke, we were</p> <p>3 talking about the limitations in randomized</p> <p>4 controlled trials, about them not being sufficiently</p> <p>5 powered; correct?</p> <p>6 A. Yes.</p> <p>7 - - -</p> <p>8 (Klinge Trial Exhibit No. 6, Article entitled</p> <p>9 "Bias-Variation Dilemma Challenges Clinical Trials:</p> <p>10 Inherent Limitations of Randomized Controlled Trials</p> <p>11 and Meta-Analyses Comparing Hernia Therapies", was</p> <p>12 marked for identification.)</p> <p>13 - - -</p> <p>14 BY MR. THOMAS:</p> <p>15 Q. Let me hand you what I have marked as Klinge</p> <p>16 Trial Exhibit Number 6. Klinge Trial Exhibit</p> <p>17 Number 6 is a paper you have just published on this</p> <p>18 topic, isn't it?</p> <p>19 A. Yes.</p> <p>20 Q. And on the first page, I guess it's a 2014</p> <p>21 paper, titled "Bias-Variation Dilemma Challenges</p> <p>22 Clinical Trials: Inherent Limitations of Randomized</p> <p>23 Controlled Trials and Meta-Analyses Comparing Hernia</p> <p>24 Therapies." And in this paper you criticize</p>

Page 170	Page 172
<p>1 randomized controlled trials and meta-analyses;</p> <p>2 correct?</p> <p>3 A. I showed the limitation of these --</p> <p>4 Q. Yes.</p> <p>5 A. -- or some questions.</p> <p>6 Q. And the ultimate conclusion of this paper,</p> <p>7 Klinge Trial Exhibit Number 6, is that registries</p> <p>8 provide better information than do randomized</p> <p>9 controlled trials or meta-analyses; correct?</p> <p>10 A. Not correct. If you believe that better is</p> <p>11 sufficient than -- that is not the purpose to have</p> <p>12 better data, but we need other data, and registries</p> <p>13 are able to provide additional data that will help us</p> <p>14 to define what is the outcome of the patients, yes,</p> <p>15 additionally.</p> <p>16 Q. Go to page 787 of Trial Exhibit Number 6.</p> <p>17 You see that? You see in the middle of the</p> <p>18 second paragraph it begins, "Observational studies</p> <p>19 nowadays can best be done with the help of</p> <p>20 registries, would provide a structure and a set of</p> <p>21 variables that are known to reflect all major</p> <p>22 influences on the patients' outcome. In this regard,</p> <p>23 it uses the same variables as the RSCT but did not</p> <p>24 restrict its data acquisition to a small group of</p>	<p>1 A. So registries should be done additionally to</p> <p>2 randomized controlled trials depending on the</p> <p>3 question, depending on the setting.</p> <p>4 Q. And registries, just for the benefit of the</p> <p>5 jury, are sets of data that are accumulated as people</p> <p>6 go through hernia surgeries, and data is completed at</p> <p>7 the time of the surgery; correct?</p> <p>8 A. The data are not complete yet. Registries</p> <p>9 have the advantage that you can include various kinds</p> <p>10 of patients, not only restricted to some standard</p> <p>11 patients, and you can include a follow-up of various</p> <p>12 times, very long period. There is -- in clinical</p> <p>13 studies, you usually finish after one day or one year</p> <p>14 or two years. So the registry offers a lot of more</p> <p>15 options to made a post-market surveillance quality</p> <p>16 control of devices; and, therefore, I think it is</p> <p>17 very interesting from manufacturer if they are</p> <p>18 interested in making their follow-up of their</p> <p>19 patients.</p> <p>20 Q. Okay. Let me show you what's been marked as</p> <p>21 Klinge Trial Exhibit Number 6.</p> <p>22 THE COURT REPORTER: It should be 7.</p> <p>23 MR. THOMAS: Seven. I'm sorry. Let me mark</p> <p>24 on it 7. Let me have that back, Doctor, please.</p>
<p style="text-align: center;">Page 171</p> <p>1 study patients."</p> <p>2 Did I read that correctly?</p> <p>3 A. Yes.</p> <p>4 Q. And the purpose of that is to talk about more</p> <p>5 robust data set from a greater number of people?</p> <p>6 MR. ANDERSON: Objection. RSCTs are outside</p> <p>7 the scope of direct.</p> <p>8 But go ahead, Dr. Klinge.</p> <p>9 THE WITNESS: So I'm not sure whether it's</p> <p>10 possible to reduce robust database, whether this</p> <p>11 covers all the questions that we address in this</p> <p>12 article.</p> <p>13 BY MR. THOMAS:</p> <p>14 Q. Do you conclude from this article that using</p> <p>15 data from a long-term registry with a large number of</p> <p>16 patients with more data is better than doing the</p> <p>17 randomized controlled trials that have been used in</p> <p>18 the past?</p> <p>19 A. I would never say that it is better in a</p> <p>20 general term. It will help us to define the outcome</p> <p>21 of the patients, better than in -- with all the</p> <p>22 limitations of randomized controlled trials, and this</p> <p>23 is expressed on several pages there.</p> <p>24 Q. Okay.</p>	<p style="text-align: center;">Page 173</p> <p>1 ---</p> <p>2 (Klinge Trial Exhibit No. 7, Article entitled</p> <p>3 "Prospective, Long-Term Comparison of Quality of Life</p> <p>4 in Laparoscopic Versus Open Ventral Hernia Repair",</p> <p>5 was marked for identification.)</p> <p>6 ---</p> <p>7 BY MR. THOMAS:</p> <p>8 Q. Doctor, let me show you what I have marked</p> <p>9 now as Klinge Trial Exhibit Number 7.</p> <p>10 Klinge Trial Exhibit Number 7 is a 2012</p> <p>11 study, first author Colavita, titled "Prospective,</p> <p>12 Long-Term Comparison of Quality of Life in</p> <p>13 Laparoscopic Versus Open Ventral Hernia Repair."</p> <p>14 Have you seen this before?</p> <p>15 A. I have seen it, but it's some time ago.</p> <p>16 Q. Okay. And if you look down at the methods,</p> <p>17 patients in this study were drawn from the</p> <p>18 international hernia registry; correct?</p> <p>19 A. Yes.</p> <p>20 Q. And it's 30 centers in the United States,</p> <p>21 Canada and Europe and Australia; correct?</p> <p>22 A. Yes.</p> <p>23 Q. And in this study the authors looked at a</p> <p>24 total of 710 hernia repairs; correct?</p>

Page 174	Page 176
<p>1 A. Yes.</p> <p>2 Q. And looked at the long-term comparison of</p> <p>3 quality of life for these 710 hernia repairs;</p> <p>4 correct?</p> <p>5 A. Yes.</p> <p>6 Q. And they used what's known as the Carolinas</p> <p>7 Comfort Scale. Are you familiar with that?</p> <p>8 A. Yes, I know it.</p> <p>9 Q. And that's -- is that similar to the SF-36</p> <p>10 questionnaire that we talked about in the previous</p> <p>11 study?</p> <p>12 A. It is another tool.</p> <p>13 Q. Okay. Do you recognize the Carolinas Comfort</p> <p>14 Scale as a way to determine the quality of life in a</p> <p>15 population of patients?</p> <p>16 A. It is a way to measure it, yeah.</p> <p>17 Q. Okay. At the time this study was published</p> <p>18 in 2012, if you look at the first page under the</p> <p>19 abstract and conclusion, to your knowledge was this</p> <p>20 the largest prospective quality of life study</p> <p>21 comparing laparoscopic ventral hernia repair with</p> <p>22 open ventral hernia repair, or do you know?</p> <p>23 A. I think that's -- that is true.</p> <p>24 Q. Okay. And so what these authors did was go</p>	<p>1 study, first full paragraph on the left, it says, "In</p> <p>2 multivariant analysis, mesh weight had no effect on</p> <p>3 pain, activity limitation, mesh sensation, or overall</p> <p>4 symptoms in the present study."</p> <p>5 Did I read that correctly?</p> <p>6 A. You read this correctly.</p> <p>7 Q. And it follows down to the end of that</p> <p>8 paragraph and it says, "In a recent small comparative</p> <p>9 study of open ventral hernia repair with light and</p> <p>10 heavyweight mesh, no difference was seen in quality</p> <p>11 of life using SF-36 with long-term follow-up."</p> <p>12 And that's the study that we looked at a</p> <p>13 minute ago, the Ladurner study; correct?</p> <p>14 A. Twenty-seven, if this is here, the reference,</p> <p>15 27? Yeah, you're right.</p> <p>16 Q. The results of this study, Klinge Exhibit 7,</p> <p>17 confirms these findings -- this long-term study from</p> <p>18 the registry, Klinge Exhibit Number 7, confirms the</p> <p>19 randomized controlled trials, the Ladurner study,</p> <p>20 that we talked about before. That's what this study</p> <p>21 finds; correct?</p> <p>22 A. It confirms that the insufficiency of this</p> <p>23 study to detect any differences. It is not possible</p> <p>24 to prove something by doing these studies, and,</p>
<p style="text-align: center;">Page 175</p> <p>1 to the registry and get the data that you have just</p> <p>2 described in your previous answers in order to make</p> <p>3 their analysis of a bigger population with more data</p> <p>4 for their findings; true?</p> <p>5 A. They are going to a registry, but the</p> <p>6 registry is not only registry because it has name.</p> <p>7 You have to go into the details, look at what</p> <p>8 variables are recorded. That was outlined in the</p> <p>9 previous paper for me.</p> <p>10 Q. If you go to page 719 of Klinge Trial Exhibit</p> <p>11 Number 7, first paragraph on the left, midway down,</p> <p>12 the authors conclude from this study, "There was no</p> <p>13 difference in mesh sensation symptoms between</p> <p>14 heavyweight or lightweight polypropylene mesh. As</p> <p>15 mentioned earlier, both were used with similar</p> <p>16 frequency and laparoscopic and open repairs."</p> <p>17 Did I read that correctly?</p> <p>18 A. Yes.</p> <p>19 Q. So across this population of 710 hernia</p> <p>20 repairs, comparing lightweight mesh as opposed to</p> <p>21 heavyweight mesh, they found no difference as to mesh</p> <p>22 sensation; correct? Is that correct?</p> <p>23 A. They described that they found -- yeah.</p> <p>24 Q. Okay. And if you go to page 721 of the same</p>	<p style="text-align: center;">Page 177</p> <p>1 therefore, there is a tremendous flaw in the</p> <p>2 interpretation of these data. You are not allowed to</p> <p>3 say that this study proves that result is similar.</p> <p>4 It is -- it is not justified to do so.</p> <p>5 Q. Okay. Let's --</p> <p>6 A. Even if it's done and even if it's published,</p> <p>7 no.</p> <p>8 Q. So you disagree with the findings in Klinge</p> <p>9 Exhibit Number -- Trial Exhibit Number 7?</p> <p>10 A. The interpretation, yeah. It's completely</p> <p>11 not justified.</p> <p>12 Q. Now, Dr. Klinge, you have contended for years</p> <p>13 that traditional use of hernia repair are</p> <p>14 overengineered -- excuse me. Start over again.</p> <p>15 Strike that.</p> <p>16 Doctor, you have contended for years that</p> <p>17 traditional meshes used for hernia repair are</p> <p>18 overengineered and is stronger than is necessary for</p> <p>19 the treatment of hernia repair; correct?</p> <p>20 A. We found this, yeah.</p> <p>21 Q. And you have argued that a lighter weight</p> <p>22 larger pore mesh is better to accomplish the same</p> <p>23 treatment of hernia repair; correct?</p> <p>24 A. Is better to?</p>

Page 178	Page 180
<p>1 Q. Yes.</p> <p>2 A. I didn't get every word of your question.</p> <p>3 Q. Let me ask it again.</p> <p>4 A. Yes.</p> <p>5 Q. You have contended that a manufacturer can</p> <p>6 design a lighter weight larger pore mesh to</p> <p>7 accomplish the same repair of a hernia as you can</p> <p>8 with a traditional heavyweight mesh; correct?</p> <p>9 A. No.</p> <p>10 Q. What did I miss? You can't get the same</p> <p>11 repair with a lighter weight larger pore mesh?</p> <p>12 A. If you're believing that you can exactly the</p> <p>13 same type of repairs with a heavyweight mesh and a</p> <p>14 large pore lightweight meshes, no, that's not true.</p> <p>15 There are indications for the different meshes.</p> <p>16 Q. Still appropriate --</p> <p>17 A. What we said is that you can improve the</p> <p>18 tissue integration by reduction of the material,</p> <p>19 making the pores larger, and that -- therefore, we</p> <p>20 developed together with Ethicon these large pore</p> <p>21 meshes, and this was confirmed in many animal trials,</p> <p>22 human explants.</p> <p>23 Q. Let's go back to P1087, please.</p> <p>24 MR. ANDERSON: Did you say 1087?</p>	<p>1 Q. And that's the mesh that you helped develop</p> <p>2 with Ethicon?</p> <p>3 A. Yes, with a pore size of 3 to 5 millimeter.</p> <p>4 Q. And you compared Vypro against the</p> <p>5 heavyweight monofilament Marlex; correct?</p> <p>6 A. In this article we took Marlex --</p> <p>7 Q. Correct.</p> <p>8 A. -- as an example of a small pore mesh.</p> <p>9 Q. And the Marlex pore size is not the same as</p> <p>10 the Prolene Soft pore size, is it?</p> <p>11 A. There are differences.</p> <p>12 Q. Yes. The Marlex mesh is typically reported</p> <p>13 as a 0.6 millimeter mesh, isn't it?</p> <p>14 A. Roughly it is assumed that it has smaller</p> <p>15 pores.</p> <p>16 Q. And the Prolene Soft Mesh is typically</p> <p>17 described as a mesh with about 2.5 millimeters;</p> <p>18 correct?</p> <p>19 A. I don't want to say that it is possible to</p> <p>20 reflect the pore size just by one figure. You know</p> <p>21 all the limitations of all these techniques, yeah.</p> <p>22 Q. They are certainly different, aren't they?</p> <p>23 The Marlex and the Prolene Soft Mesh are very</p> <p>24 different in their characteristics?</p>
<p style="text-align: center;">Page 179</p> <p>1 MR. THOMAS: Yes. It's the PowerPoint.</p> <p>2 MR. ANDERSON: I know. We just have a stack</p> <p>3 of documents, so I have to find it.</p> <p>4 MR. THOMAS: Strike that. I'm not going to</p> <p>5 do that one anyway.</p> <p>6 MR. ANDERSON: Okay.</p> <p>7 MR. THOMAS: Let's go to P0260, which is a</p> <p>8 2002 study with Dr. Klinge and Dr. Klosterhalfen.</p> <p>9 MR. ANDERSON: Okay.</p> <p>10 BY MR. THOMAS:</p> <p>11 Q. Doctor, on direct examination you discussed</p> <p>12 Plaintiff's Exhibit 0260 in connection with your</p> <p>13 earlier work on talking about the impact of polymer</p> <p>14 pore size on the interface scar formation in a rat</p> <p>15 model; correct?</p> <p>16 A. That is correct.</p> <p>17 Q. And you used this article to talk about your</p> <p>18 findings about what happens with the smaller pore</p> <p>19 heavyweight mesh, correct, as compared to the</p> <p>20 heavyweight large pore mesh?</p> <p>21 A. Yes.</p> <p>22 Q. And in this study, the lightweight large pore</p> <p>23 mesh that you use as a comparator is your Vypro mesh?</p> <p>24 A. Yes.</p>	<p style="text-align: center;">Page 181</p> <p>1 A. Yes. The soft Prolene mesh is more open than</p> <p>2 the Marlex.</p> <p>3 Q. Okay. Doctor, you cannot point to a mesh</p> <p>4 today for use in the pelvic floor that has no risks</p> <p>5 of infection, can you?</p> <p>6 A. There is no study -- if you -- no risks means</p> <p>7 no complication at all? No, there is no way.</p> <p>8 MR. ANDERSON: I'll just say objection;</p> <p>9 outside the scope of direct.</p> <p>10 BY MR. THOMAS:</p> <p>11 Q. And, Doctor, you do not know of any mesh</p> <p>12 construction that leads to a lower -- strike that.</p> <p>13 Doctor, you do not know of any mesh</p> <p>14 construction for use in the pelvic floor that leads</p> <p>15 to a lower erosion rate than Prolift; correct?</p> <p>16 A. I know that there are -- that there are ways</p> <p>17 to reduce the risk. There are no clinical</p> <p>18 comparative studies, to my knowledge.</p> <p>19 Q. Doctor, you know of -- you do not know of any</p> <p>20 mesh construction today for use in the pelvic floor</p> <p>21 that leads to a lower erosion rate than Prolift;</p> <p>22 correct?</p> <p>23 MR. ANDERSON: Objection; asked and answered.</p> <p>THE WITNESS: A mesh construction which</p>

Page 182	Page 184
<p>1 follows our criteria reducing the material, 2 making it larger, it will reduce the erosion 3 rate, but there is no comparative study 4 available.</p> <p>5 BY MR. THOMAS:</p> <p>6 Q. Let me ask the question again, Doctor.</p> <p>7 Are you aware of any mesh construction for 8 use in the pelvic floor that leads -- strike that.</p> <p>9 Are you aware of any mesh constructions 10 available for use today in the pelvic floor that 11 leads to lower erosion rates than Prolift?</p> <p>12 MR. ANDERSON: Objection; asked and answered 13 for the third time.</p> <p>14 THE WITNESS: As I don't know any comparative 15 study directly comparing different mesh 16 structures, I only can say that there are mesh 17 structures with lower risk than the Prolift.</p> <p>18 BY MR. THOMAS:</p> <p>19 Q. But you are --</p> <p>20 A. For erosion.</p> <p>21 Q. But you are aware of no studies that prove 22 that point; correct?</p> <p>23 A. No clinical studies proving this.</p> <p>24 Q. Is that true?</p>	<p>1 A. No comparative studies are available, to my 2 knowledge.</p> <p>3 Q. Okay. Can you name one mesh on the market 4 today that you think that the benefits outweigh the 5 risks for use in treatment of pelvic organ prolapse?</p> <p>6 A. No. And to answer this question, it is 7 impossible in this general statement. It depends on 8 the patient. It depends on the indication. Then you 9 have to specify which implant under which conditions. 10 So it is not possible to answer this question.</p> <p>11 MR. THOMAS: Let's take a break for a second.</p> <p>12 THE VIDEOGRAPHER: We are off the record.</p> <p>13 The time is 12:55 p.m.</p> <p>14 (A recess was taken from 12:55 p.m. until 1:00 p.m.)</p> <p>15 THE VIDEOGRAPHER: We are back on the record.</p> <p>16 The time is 1:00 p.m.</p> <p>17 BY MR. THOMAS:</p> <p>18 Q. Doctor, can you tell the jury one product on 19 the market for the treatment of pelvic organ prolapse 20 that you think is better than the Prolift?</p> <p>21 A. In regard to the effective porosity, for 22 example, and the strain, I know that DynaMesh has a 23 device that is superior to the Prolift.</p> <p>24 Q. And the DynaMesh is not -- is that the only</p>
<p style="text-align: center;">Page 183</p> <p>1 A. That is true.</p> <p>2 Q. Okay. And you are aware of no mesh 3 construction that causes less chronic pain in the 4 pelvic floor than Prolift; true?</p> <p>5 A. No clinical study comparing different mesh 6 materials and showing differences are available up to 7 now.</p> <p>8 Q. And you're aware of no mesh design for use in 9 the pelvic floor that provides lower contracture 10 rates than the Prolift; true?</p> <p>11 A. No, that's not true. I'm well-aware of mesh 12 criteria for a safer mesh design as we outlined it, 13 less material, larger pores and no pore collapse. 14 This will make a safer mesh design.</p> <p>15 Q. Are you aware of any mesh design available 16 for use today in the pelvic floor that provides lower 17 contraction rates than the Prolift?</p> <p>18 A. There are mesh constructions which are closer 19 to these criteria for mesh design -- for safe mesh 20 design.</p> <p>21 Q. Are you aware of any comparative studies 22 which show that there is a mesh available for use in 23 the pelvic floor today that provides lower 24 contracture rates than the Prolift?</p>	<p style="text-align: center;">Page 185</p> <p>1 one that you think is better for use in the pelvic 2 floor --</p> <p>3 A. I know --</p> <p>4 Q. -- than the Prolift?</p> <p>5 A. I know there is a huge variety. I'm not sure 6 which is -- what is on the market, actually, but I 7 know that there are various designs of meshes; but we 8 didn't make a systematic testing of all devices that 9 are on the market or have been on the market.</p> <p>10 Q. And the DynaMesh is not available for sale in 11 the United States; correct?</p> <p>12 A. I think so, but I'm not informed about the --</p> <p>13 Q. You think that it is available?</p> <p>14 MR. ANDERSON: Let him finish his answer, if 15 you wouldn't find.</p> <p>16 Go ahead.</p> <p>17 THE WITNESS: I think it is not available, 18 but I'm not knowing all the details which product 19 is in which country on the market.</p> <p>20 BY MR. THOMAS:</p> <p>21 Q. Let me --</p> <p>22 A. I'm not involved in this business.</p> <p>23 Q. Let me ask the question this way so it's 24 clear. We had some interruptions.</p>

Page 186	Page 188
<p>1 You don't know whether DynaMesh, manufactured 2 by FEG, is available for sale in the United States, 3 do you?</p> <p>4 A. I don't know.</p> <p>5 Q. Okay. And you said that DynaMesh is better 6 than Prolift from the perspective of effective 7 porosity?</p> <p>8 A. As we measure it, as we can show with our 9 measurements it has a higher effective porosity, it 10 has a higher stability when put to strain.</p> <p>11 Q. But you agree that there are no clinical 12 long-term studies that prove the superiority of the 13 DynaMesh over the Prolift for the treatment of pelvic 14 organ prolapse?</p> <p>15 A. There are at all no comparative studies 16 showing the superiority of any of these, and, again, 17 it is not possible to do so. I don't see a good way 18 to do so.</p> <p>19 Q. And you're aware of no studies that 20 demonstrate that PVDF mesh, which is DynaMesh, is 21 superior to the polypropylene mesh used in Prolift; 22 correct?</p> <p>23 A. We know from many histological studies that 24 the tissue reaction to PVDF is better than the tissue</p>	<p>1 A. I don't have an own -- at the moment I don't 2 have an own collection of pelvic floor meshes.</p> <p>3 Q. You collect hernia meshes; correct?</p> <p>4 A. We had collected, but meanwhile the -- all 5 the tissue samples are stored in a biotissue bank 6 from the university from the institute for pathology 7 centrally where they are stored under GCP conditions.</p> <p>8 Q. Okay. But you've never asked your department 9 that deals with the pelvic floor to preserve and 10 collect meshes that have been removed in explants; 11 correct?</p> <p>12 A. No. It's no longer an issue that I -- that 13 I'm asked to collect these. They are sent all to 14 this bio bank; and when you want to make a research, 15 then you can ask for getting these samples.</p> <p>16 Q. Now, to your knowledge, there's only one mesh 17 manufacturer in the world that makes mesh made of 18 PVDF for the treatment of pelvic organ prolapse; 19 correct?</p> <p>20 A. In the moment, I think this is true.</p> <p>21 Q. And that's FEG?</p> <p>22 A. This is true.</p> <p>23 Q. And that's the German mesh manufacturer 24 headquartered here in Aachen?</p>
<p style="text-align: center;">Page 187</p> <p>1 reaction to the polypropylene, less inflammation, 2 less scarring when you are using the PVDF.</p> <p>3 Q. And the PVDF -- strike that.</p> <p>4 You're aware of no studies in humans that 5 demonstrate that PVDF mesh is superior to 6 polypropylene mesh used in Prolift for pelvic floor 7 repair; correct?</p> <p>8 A. Our studies in human explants always 9 confirmed the superiority of PVDF as a polymer to be 10 integrated in tissue.</p> <p>11 Q. And is this in hernia explants?</p> <p>12 A. This is in hernia explants.</p> <p>13 Q. And these -- this is the hernia explants that 14 you've reviewed with Dr. Klosterhalfen in his 15 collection?</p> <p>16 A. Yes.</p> <p>17 Q. And have you looked at any PVDF mesh explants 18 from the pelvic floor?</p> <p>19 A. Up to now I never saw one.</p> <p>20 Q. Okay.</p> <p>21 A. Which is a good sign.</p> <p>22 Q. And just so the record is clear, you don't 23 maintain your own collection of mesh removed from the 24 pelvic floor; correct?</p>	<p style="text-align: center;">Page 189</p> <p>1 A. Yes.</p> <p>2 Q. And you helped PVDF -- excuse me. Strike 3 that.</p> <p>4 You helped FEG develop its PVDF mesh, didn't 5 you?</p> <p>6 A. Yes.</p> <p>7 Q. And you're named on the patent for PVDF mesh?</p> <p>8 A. Yes.</p> <p>9 Q. You've done research for FEG since 1994; 10 correct?</p> <p>11 A. That is correct.</p> <p>12 Q. And Dr. Oberlinski is one of FEG's owners; 13 correct?</p> <p>14 A. That is correct.</p> <p>15 Q. And he used to work with you at the 16 university; correct?</p> <p>17 A. This again?</p> <p>18 Q. He used to work -- Dr. Oberlinski used to 19 work at the university, didn't he?</p> <p>20 A. When we started our collaboration, he worked 21 for the institute for textile engineering at the 22 university, but then later on he changed to the 23 company.</p> <p>24 Q. It was Dr. Oberlinski who first told you that</p>

Page 190	Page 192
1 there are several textile options available to change 2 mesh? 3 A. Yes. 4 Q. Now, you've been a paid consultant by FEG 5 since 1998 or 1999. Is that true? 6 A. No. I guess it was later on. It was after 7 the contract finished with the -- with Ethicon. 8 Q. And to this day you're compensated annually 9 by FEG; correct? 10 A. Correct. 11 Q. And they pay you about 30,000€ a year? 12 A. Yeah. 13 Q. They determine how much they'll pay you each 14 year depending on how well the company does that 15 year; correct? 16 A. Yes. 17 Q. And you've spoken at conferences sponsored 18 solely by FEG; correct? 19 A. Yes. 20 Q. And you do that routinely? You regularly 21 attend conferences around the world on behalf of FEG; 22 correct? 23 A. I routinely attend conferences, and I am 24 invited all over the world. Most of these, far most	1 MR. ANDERSON: Okay. Take a short break. 2 THE VIDEOGRAPHER: We are off the record. 3 The time is 1:10 p.m. 4 (A recess was taken from 1:09 p.m. until 1:31 p.m.) 5 THE VIDEOGRAPHER: We are back on the record. 6 The time is 1:31. 7 REDIRECT EXAMINATION 8 BY MR. ANDERSON: 9 Q. Dr. Klinge, do you remember when counsel was 10 asking you some questions about the PVDF mesh and 11 PVDF fibers? 12 A. There has been several questions, but I 13 remember. 14 Q. Okay. If we could go to Plaintiff's Exhibit 15 697 right here. It's the Otto article. If we could 16 go over a few pages to the mesh. 17 MR. ANDERSON: No. Blow up the top part. 18 Actually, no, no. Next page. 19 MR. KAUFFMANN: Next page? 20 MR. ANDERSON: Okay. Yeah. Blow up the 21 whole top part. 22 BY MR. ANDERSON: 23 Q. Doctor, the mesh on the far right side, the 24 DynaMesh, is that the mesh that you were talking with
1 of these invitations are not linked to the FEG. So 2 it is an exception if I do it on the -- on the 3 invitation of the FEG. This is a rare exception. 4 Q. And your picture is on the FEG website, isn't 5 it? 6 A. Maybe. To be fair, I never have looked to 7 this website. I didn't saw any need to do so. 8 Q. And you're going to teach next week in 9 Baden-Baden at a class sponsored by FEG, aren't you? 10 A. Yeah. 11 Q. The International Masterclass for 12 Laparoscopic Hernia Repair; correct? 13 A. Yes. 14 Q. And that's a seminar sponsored by the FEG? 15 A. Yeah. It was an invitation by Professor 16 Berger, who was the former head of the German 17 Society, and we did it for the fourth time or the 18 fifth time. 19 Q. And the agenda for the hernia session is on 20 the FEG website, isn't it? 21 A. As I told you, I'm not a visitor of this 22 website. 23 MR. THOMAS: That's all the questions I have. 24 Thank you, Doctor.	1 counsel about that's made by FEG? 2 A. Yes. This is a PVDF mesh made by FEG. 3 Q. And does FEG -- FEG make meshes made out of 4 this PVDF material for pelvic organ prolapse? 5 A. Yes. 6 Q. And just explain quickly for the jury what 7 PVDF is as a polymer, as a material. 8 A. PVDF is a plastic material like -- as 9 polypropylene is, but it has -- it consists of two 10 fewer atoms. So it has some other molecules inside, 11 and it has more stability than the polypropylene. 12 Q. How long have you known about PVDF as an 13 alternative polymer to polypropylene for surgical 14 meshes? 15 A. We, actually, started to think about it in 16 1997. When we finished the Vypro, we knew that it 17 was possible to made a mesh with large pores. But 18 Vypro consists of five filaments, and to reduce 19 further on the risk for bacterial infection, we 20 wanted to construct it as a monofilament. And, 21 therefore, we have been looking for the best material 22 for the construction of a monofilament large pore 23 meshes. And there it came up that PVDF may be the 24 best.

Page 194	Page 196
<p>1 And we approached Ethicon to join this 2 activity further on. We asked for some grants to do 3 this research, and, fortunately, we got the 4 permission to do this project by our university and 5 we got some further grants to work on PVDF meshes; 6 but, unfortunately, Ethicon denied to develop meshes 7 made of PVDF, though they provided us with one PVDF 8 mesh that is made by Ethicon.</p> <p>9 Q. So did Ethicon have an opportunity to work 10 with you and FEG to develop PVDF meshes during this 11 time period?</p> <p>12 A. Obviously they had a mesh, but they didn't 13 want to go into this project to develop PVDF meshes, 14 but they were asked, but they denied. They didn't 15 want to do so.</p> <p>16 Q. Have you studied the differences in the 17 tissue reaction in patients' tissue of polypropylene 18 versus a PVDF?</p> <p>19 A. Yeah. We did a several --</p> <p>20 Q. Okay.</p> <p>21 MR. ANDERSON: Pull up Plaintiff's Exhibit 22 770, which may help us with this discussion.</p> <p>23 - - -</p> <p>24 (Plaintiff's Exhibit No. PLT0770, Article</p>	<p>1 Ethicon? 2 A. Yes. 3 Q. Okay. 4 MR. ANDERSON: Let's go to Exhibit 3354. Oh, 5 it's the wrong one. I need the translation. 6 - - - 7 (Plaintiff's Exhibit No. P3355, English 8 Translation of Plaintiff's Exhibit 3354, Patent for 9 PVDF mesh, was marked for identification.) 10 - - - 11 BY MR. ANDERSON: 12 Q. I'm showing you what has been marked as 13 Plaintiff's Exhibit 3355. What is this, Doctor? 14 A. This is a patent from Ethicon. 15 Q. Okay. And what's it a patent for? 16 A. It's a patent for a PVDF mesh. 17 Q. Is this something that you've reviewed and 18 relied upon in forming some of your opinions here? 19 A. Yes. 20 Q. If you'll turn over to page 12. 21 MR. THOMAS: Show my objection to this 22 witness offering any testimony about this 23 document. It's well beyond the scope of his 24 expertise. The document speaks for itself.</p>
<p style="text-align: center;">Page 195</p> <p>1 entitled "New Polymer for Intra-Abdominal Meshes - 2 PVDF Copolymer", was marked for identification.) 3 - - -</p> <p>4 BY MR. ANDERSON:</p> <p>5 Q. I'm showing you what's been marked as 6 Plaintiff's Exhibit 0770. Is this some of the 7 research that you were just describing where you were 8 looking at tissue response to PVDF?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. Tell the jury what your conclusions 11 were after looking at this PVDF study.</p> <p>12 A. In this study, this study clearly confirms 13 that the tissue reaction to the PVDF is better than 14 for the polypropylene.</p> <p>15 Q. Who provided you with the PVDF meshes for 16 testing in this study?</p> <p>17 A. It was a PVDF mesh made by Ethicon.</p> <p>18 MR. ANDERSON: Let's go to the end of the 19 document under the conclusion section. Go back. 20 There. "This study was supported..."</p> <p>21 No. Down below. Next paragraph.</p> <p>22 BY MR. ANDERSON:</p> <p>23 Q. Is this what you're discussing, that this 24 PVDF study was, in fact, supported and funded by</p>	<p style="text-align: center;">Page 197</p> <p>1 There's nothing special he can bring to the 2 issues raised by this patent.</p> <p>3 MR. ANDERSON: Yeah. And I didn't ask him 4 anything about PVDF on direct. You chose to. 5 You opened the door. We're going to drive 6 through it.</p> <p>7 BY MR. ANDERSON:</p> <p>8 Q. Okay. So if you will look at page 12 under 9 claims.</p> <p>10 A. Yes.</p> <p>11 Q. What does it say with regard to the pore 12 sizes for PVDF mesh?</p> <p>13 A. Basic structure should have a pore size with 14 a range of 1.5 to 8.0 millimeter, so to be extremely 15 large, covering 90 percent of the total area of the 16 pores.</p> <p>17 Q. Okay. Let's go to Plaintiff's Exhibit 1087, 18 which you've already seen. Plaintiff's Exhibit 1087. 19 He can have it. I gave him a copy. Plaintiff's 20 Exhibit 1087.</p> <p>21 You're okay. You don't need to go there. 22 It's going to come up on the screen.</p> <p>23 Is this a document we reviewed earlier during 24 your direct examination?</p>

Page 198	Page 200
<p>1 A. Yes.</p> <p>2 Q. Okay. From 2008?</p> <p>3 A. From 2008. Ethicon document.</p> <p>4 Q. Okay.</p> <p>5 MR. ANDERSON: If you'd go to the slide.</p> <p>6 MR. KAUFFMANN: Got it.</p> <p>7 MR. ANDERSON: Yes. Blow up that bottom left.</p> <p>8</p> <p>9 BY MR. ANDERSON:</p> <p>10 Q. In this Ethicon presentation, what is this?</p> <p>11 A. This is a PVDF copolymer mesh.</p> <p>12 Q. And do you know -- and based upon your review</p> <p>13 of the patent and your review of these documents, did</p> <p>14 Ethicon have a brand name for this PVDF mesh?</p> <p>15 A. No. I don't think that they marketed it.</p> <p>16 Q. No. Not marketed it but --</p> <p>17 A. Yeah.</p> <p>18 Q. -- did they have a brand name for it?</p> <p>19 A. Brand name was Pronova. Pronova was the name</p> <p>20 of this.</p> <p>21 Q. Do you have any information as to whether or</p> <p>22 not Ethicon ever chose to sell their Pronova mesh</p> <p>23 made out of PVDF?</p> <p>24 A. So far I know, they never brought it to the</p>	<p>1 right there.</p> <p>2 MR. THOMAS: That's not what it says. I</p> <p>3 object to showing this document to the jury,</p> <p>4 admission of this document and any testimony</p> <p>5 about this document. The document speaks by</p> <p>6 itself, and this witness is not qualified, with</p> <p>7 no foundation to give any comment about the</p> <p>8 document.</p> <p>9 BY MR. ANDERSON:</p> <p>10 Q. Dr. Klinge, did you, in fact, have this</p> <p>11 document in your own files when you worked with</p> <p>12 Ethicon?</p> <p>13 A. Yes.</p> <p>14 Q. And did you produce that to Ethicon when they</p> <p>15 requested all of your files?</p> <p>16 A. Yes.</p> <p>17 Q. So this is a document that you received while</p> <p>18 you were consulting with them?</p> <p>19 A. Yes.</p> <p>20 Q. Great. And underneath there it says</p> <p>21 Christoph Walther. Is that one of the Ethicon</p> <p>22 employees that you would have worked with?</p> <p>23 A. Yes.</p> <p>24 Q. And in the middle there where it says,</p>
<p>1 market.</p> <p>2 Q. And from your reading of the PowerPoint, what</p> <p>3 was the discussion and the reason for this PowerPoint</p> <p>4 being given at Ethicon?</p> <p>5 MR. THOMAS: Objection; state of mind,</p> <p>6 knowledge of Ethicon.</p> <p>7 BY MR. ANDERSON:</p> <p>8 Q. What was discussed in this Thunder PowerPoint</p> <p>9 by Ethicon?</p> <p>10 MR. THOMAS: Same objection.</p> <p>11 THE WITNESS: The entire project was to</p> <p>12 evaluate whether the use of PVDF would make a</p> <p>13 safer approach -- would make a safer device for</p> <p>14 the use in the pelvic floor.</p> <p>15 ---</p> <p>16 (Plaintiff's Exhibit No. P3184, Letter to</p> <p>17 Quentin from Christoph Walther, Bates stamped</p> <p>18 HMESH_ETH_00379723, was marked for identification.)</p> <p>19 ---</p> <p>20 BY MR. ANDERSON:</p> <p>21 Q. Let's look at Plaintiff's Exhibit 3184. This</p> <p>22 is a document that you have seen before, Dr. Klinge.</p> <p>23 MR. ANDERSON: If you'll highlight the</p> <p>24 section that says "In extremely, this patient,"</p>	<p>1 "Pronova monofilaments are an extremely good</p> <p>2 candidate as implant material, very high flexibility</p> <p>3 and low bending stiffness" --</p> <p>4 A. Yes.</p> <p>5 Q. -- "and without loss of tensile strength in</p> <p>6 contrast to polypropylene and long-term stability --</p> <p>7 long-term stability in human body."</p> <p>8 Do you agree with those statements by</p> <p>9 Ethicon?</p> <p>10 A. Yes.</p> <p>11 Q. Do you have an opinion as to whether or not</p> <p>12 polypropylene mesh is -- creates greater inflammatory</p> <p>13 reaction in tissues than PVDF mesh?</p> <p>14 A. Polypropylene in general produces more</p> <p>15 inflammation, more scarring than PVDF.</p> <p>16 Q. You were asked by Mr. Thomas on</p> <p>17 cross-examination whether polypropylene has been used</p> <p>18 in the human body for hernia mesh since 1962. Do you</p> <p>19 remember that question?</p> <p>20 A. Yes.</p> <p>21 Q. And has polypropylene been used in the human</p> <p>22 pelvis of women for pelvic organ prolapse since 1962?</p> <p>23 A. No. It's less than ten years.</p> <p>24 Q. He also pulled out the -- that 240 meters of</p>

Page 202	Page 204
<p>1 suture material and asked you whether or not that 2 much material goes into some of the meshes in the 3 hernia -- for hernia repair. Do you remember that 4 part of your questioning?</p> <p>5 A. Yes.</p> <p>6 Q. Is there a difference between that amount of 7 material in the abdominal wall than that amount of 8 material in a woman's vaginal space?</p> <p>9 A. Definitely. The use of a mesh in the 10 abdominal wall, we don't have to consider some 11 forces. It's laying there flat, usually beneath the 12 muscles. You don't have any tension to any arms or 13 something like this. There are less nerves. There 14 are no organs with direct contact to the mesh that 15 can be damaged by this. So it is more easy -- if you 16 have some complications, some infection, it is 17 quite -- much more easy to remove it and to repair 18 the damage after a mesh complication.</p> <p>19 Q. Easier to remove the hernia than the pelvic 20 organ prolapse, is that what you're saying?</p> <p>21 A. It is easier to remove the mesh.</p> <p>22 MR. THOMAS: Let me move to strike his 23 testimony about mesh in the pelvic floor as being 24 beyond the area of his expertise.</p>	<p>1 Q. Go right ahead, Doctor.</p> <p>2 A. When using -- when I would use a new device, 3 I'm dependent on the information that is provided by 4 the manufacturer for the long-term risks or for the 5 risks that are connected to this device. There is no 6 other way to get this information.</p> <p>7 Q. If you're a surgeon that's putting in what 8 you characterize as a relatively new device, if the 9 manufacturer knew that there was a serious long-term 10 risk of chronic debilitating pain, would you expect 11 them to pass that information along to you?</p> <p>12 A. Yes, I would.</p> <p>13 MR. THOMAS: Objection to foundation.</p> <p>14 THE WITNESS: And in parallel, he has to stop 15 selling it.</p> <p>16 BY MR. ANDERSON:</p> <p>17 Q. And if a manufacturer was aware of serious 18 adverse events of life-altering untreatable erosions, 19 would you expect them to pass that along to you as a 20 surgeon?</p> <p>21 MR. THOMAS: Objection.</p> <p>22 A. Yes.</p> <p>23 MR. THOMAS: Argumentative.</p> <p>24 BY MR. ANDERSON:</p>
<p style="text-align: center;">Page 203</p> <p>1 MR. ANDERSON: You sure asked him a lot of 2 questions about it, but okay. Let's move on.</p> <p>3 BY MR. ANDERSON:</p> <p>4 Q. You were asked some questions about 5 consenting your patients when you were a hernia 6 surgeon. Do you remember that?</p> <p>7 A. Yes.</p> <p>8 Q. And you were asked questions about what risks 9 you would pass along to your patients; correct?</p> <p>10 A. Yes.</p> <p>11 Q. Can you pass along a risk if you're not told 12 about it by the manufacturer?</p> <p>13 A. No.</p> <p>14 Q. If you were a surgeon who's implanting a new 15 surgical device, do you expect the manufacturer to 16 pass along information they have about serious 17 adverse events that could affect that risk-benefit 18 discussion with your patients?</p> <p>19 A. Definitely.</p> <p>20 MR. THOMAS: Objection; foundation, beyond 21 the scope.</p> <p>22 MR. ANDERSON: It's direct response to the 23 cross-exam.</p> <p>24 BY MR. ANDERSON:</p>	<p style="text-align: center;">Page 205</p> <p>1 Q. Okay. Wait until he does his objection --</p> <p>2 A. Sorry.</p> <p>3 Q. -- and then you can answer because it's 4 messing up the record, and it's harder for her to 5 type.</p> <p>6 A. Sorry.</p> <p>7 MR. THOMAS: Do you want to ask the question 8 again?</p> <p>9 MR. ANDERSON: I think I liked it.</p> <p>10 THE COURT REPORTER: You might need to --</p> <p>11 MR. ANDERSON: Because he interrupted me?</p> <p>12 MR. THOMAS: I didn't want mean to.</p> <p>13 MR. ANDERSON: Well, you already did.</p> <p>14 MR. THOMAS: I'm sorry. Doing the best I 15 can, man.</p> <p>16 BY MR. ANDERSON:</p> <p>17 Q. If a manufacturer is aware of serious 18 lifelong risk of recurrent erosions that can't be 19 treated, would you, as a surgeon, want to know that?</p> <p>20 A. Yes.</p> <p>21 Q. If a manufacturer is aware that their product 22 can create a serious adverse long-term risk of 23 dyspareunia or painful sexual relations, would you 24 expect them to pass that along to you?</p>

Page 206	Page 208
<p>1 A. Yes.</p> <p>2 Q. If a manufacturer was aware that in certain 3 patients, like young patients or sexually active 4 patients, that in those patients they shouldn't have 5 that device implanted, would you expect them to pass 6 that along to you?</p> <p>7 A. Yes.</p> <p>8 MR. THOMAS: Just show my objection to the 9 whole line as being beyond his whole line of 10 expertise as a hernia surgeon.</p> <p>11 MR. ANDERSON: And that's fine because, just 12 for the judge's purposes when we go to argue 13 this, Mr. Thomas asked numerous questions about 14 passing on the risk-benefit information and that 15 the manufacturer didn't need to tell him these 16 things because he already knew it; and so let's 17 go through some of the things on redirect of what 18 he would like to know from the manufacturer, and 19 so that's what I'm attempting to do now. So 20 we'll note your objection and my response.</p> <p>21 BY MR. ANDERSON:</p> <p>22 Q. If the manufacturer is aware that their 23 device should not be used with certain patients, 24 certain indications, would you expect them to pass</p>	<p>1 THE WITNESS: There is no way to place it 2 completely tension-free, and I believe there is 3 no one who will really think of it as an option.</p> <p>4 BY MR. ANDERSON:</p> <p>5 Q. When you saw those arms being pulled through 6 the woman's groin from her vaginal incision, was 7 there tension being placed on those arms?</p> <p>8 A. Definitely. Uniaxial tension, as it was done 9 in our measurements and it was done -- as it was done 10 in the drawings from Ethicon and in the study done by 11 Ethicon.</p> <p>12 Q. And Mr. Thomas mentioned that when you did 13 your uniaxial testing with Professor Mühl that you 14 held one end and you pulled on the other end; 15 correct?</p> <p>16 A. Yes.</p> <p>17 Q. Is that exactly what the surgeon was doing in 18 that DVD video with the arms?</p> <p>19 A. Yes.</p> <p>20 Q. You were asked some questions about your 21 testing with Professor Mühl by Mr. Thomas about 22 whether or not this -- the porosity setup and 23 investigation you had done accounted for pelvic floor 24 forces. Do you remember that?</p>
<p>1 that information along to you?</p> <p>2 A. Yes.</p> <p>3 MR. THOMAS: Objection; vague.</p> <p>4 THE WITNESS: Yes, of course.</p> <p>5 BY MR. ANDERSON:</p> <p>6 Q. For instance, if a manufacturer knew that a 7 particular type of hernia or a particular type of 8 prolapse, it would be inappropriate to treat with 9 that device, would you expect them to pass that along 10 to you?</p> <p>11 MR. THOMAS: Objection; compound.</p> <p>12 THE WITNESS: Yes.</p> <p>13 BY MR. ANDERSON:</p> <p>14 Q. Mr. Thomas said something on cross about the 15 Prolift being implanted tension-free. You've seen 16 the DVD; correct?</p> <p>17 A. Yes.</p> <p>18 Q. You've seen the internal documents by 19 Ethicon?</p> <p>20 A. Yes.</p> <p>21 Q. Is there any way that a Prolift can actually 22 be implanted tension-free in a woman?</p> <p>23 MR. THOMAS: Objection; not an expert in the 24 surgical procedure.</p>	<p>1 Page 207</p> <p>1 A. Yes.</p> <p>2 Q. As you looked at the pores in the DVD and the 3 tension placed on the mesh arms by the surgeon, are 4 those pores deformed before any forces from the 5 pelvis are being placed on the mesh?</p> <p>6 MR. THOMAS: Objection. Again, not familiar 7 with the surgical procedure and what's going on 8 inside.</p> <p>9 THE WITNESS: In these arms there is no 10 interference with some other forces from the 11 pelvic floor, and there is no interference with 12 some ingrowing tissue which will occur later on.</p> <p>13 BY MR. ANDERSON:</p> <p>14 Q. So were the pores irreversibly deformed on a 15 Prolift arm even before the woman's vaginal incision 16 is closed?</p> <p>17 A. Yes.</p> <p>18 MR. THOMAS: Objection. That's beyond the 19 scope of this witness's ability to testify, any 20 expertise, any disclosed opinions or testing.</p> <p>21 BY MR. ANDERSON:</p> <p>22 Q. And your answer was?</p> <p>23 A. Yes.</p> <p>24 Q. Thank you.</p>

Page 210	Page 212
<p>1 He also -- Mr. -- the counsel also pointed 2 out from these articles -- he pointed out to two 3 sections on the 2007 article and the 2013 article, 4 these sections that says clinical studies have to 5 prove whether or not effective porosity and meshes 6 with high effective porosity will actually result in 7 improved patient complications. Do you remember 8 that?</p> <p>9 A. Yes.</p> <p>10 Q. And he asked you, "You haven't done any 11 clinical studies to look at this, have you?" Do you 12 recall that question?</p> <p>13 A. Yes.</p> <p>14 Q. Are you a mesh manufacturer, Doctor?</p> <p>15 A. No.</p> <p>16 Q. After Ethicon circulated these two e-mails in 17 2008 and again in 2010, circulating your and Mühl's 18 testing, did you see anywhere in the Ethicon 19 documents where they did any clinical studies to look 20 at pore deformation?</p> <p>21 A. No, I didn't find any hint for this.</p> <p>22 Q. Do you see anywhere in the documents, all the 23 thousands of documents you reviewed, all the 24 depositions of all the Ethicon witnesses you</p>	<p>1 experimental results. And if you have another 2 polymer, yeah, you have to adopt it to this polymer 3 after having the -- making this investigation.</p> <p>4 Q. Thank you. Let me go to another question 5 he -- series of questions you were asked.</p> <p>6 He put two articles in front of you by Jan 7 Deprest, and counsel said, "Are you aware of other 8 scientists out there who may disagree with your 1 9 millimeter?" Do you remember that part of the 10 questioning?</p> <p>11 A. Yes.</p> <p>12 Q. Those two articles by Jan Deprest, is Jan 13 Deprest an Ethicon consultant?</p> <p>14 A. So far I know, yes.</p> <p>15 Q. And if Jan Deprest said that 75 microns is 16 efficient for good, healthy tissue ingrowth and it 17 will resist scar plates, is that consistent or 18 inconsistent with Ethicon's own documents?</p> <p>19 MR. THOMAS: Object to the form of the 20 question. Object to foundation.</p> <p>21 THE WITNESS: It will be inconsistent. If 22 you really believe that it is possible to -- or 23 the ingrowths of healthy tissue is possible for 24 these low pore size, then it would be</p>
Page 211	Page 213
<p>1 reviewed, or any scientific literature where Ethicon 2 ever looked at what the impact on patients would be 3 after forces were placed on the arms? Do you see 4 that anywhere?</p> <p>5 A. No.</p> <p>6 Q. You were asked why your machine was set for 7 1,000 microns for polypropylene in terms of a 8 critical limit of the distance between the fibers, 9 and you were asked why PVDF was set at 600 microns. 10 Do you remember that?</p> <p>11 A. Yes.</p> <p>12 Q. Why?</p> <p>13 A. The basis for these two figures, 600 and 14 1,000 microns, have been our investigations of the 15 tissues, because we have seen that around the fiber 16 made of PVDF, the inflammatory reaction is -- is 17 attenuated and there is less scar and that the pores 18 are filled with fat even when the size of the hole of 19 the pore is only 600 microns. And, therefore, 20 because this -- this measurement by Professor Mühl 21 was intended to predict the risk for these scar 22 contraction and scar integration in the pores; 23 therefore, we adopted this to 600 microns for PVDF 24 and 1 millimeter for polypropylene. It fits to our</p>	<p>1 inconsistent. The Ethicon people clearly stated 2 it on several pages in several documents that we 3 have to consider a pore size of 3 millimeters or 4 at least 1 millimeter and far beyond.</p> <p>5 BY MR. ANDERSON:</p> <p>6 Q. And was the product that was developed by you 7 and Ethicon, the Vypro mesh, did it have pore sizes 8 less than 75 microns?</p> <p>9 A. No.</p> <p>10 Q. Did it have pore sizes larger than 1,000 11 microns?</p> <p>12 A. So the pores -- the area of the large pores 13 is considerably higher, and the diameter of these 14 pores is between 3 and 5 millimeter.</p> <p>15 Q. Have you seen anywhere in the Ethicon 16 documents out of all of the ones you've reviewed or 17 out of the ten years of consulting with them or all 18 of the depositions that you saw anywhere where 19 Ethicon said, "At 75 microns we can prevent fibrotic 20 bridging"?</p> <p>21 A. Nowhere.</p> <p>22 Q. You were asked another series of questions 23 about whether there were any RCTs that you could 24 point to randomized controlled trials of Prolift in</p>

Page 214	Page 216
<p>1 order to prove the safety of its device. Do you 2 remember that? 3 A. Yes. 4 Q. You were asked whether you had conducted any 5 studies or knew of any studies, randomized controlled 6 trials, to prove the safety of Prolift. Do you 7 remember that? 8 A. Yes. 9 Q. Do you see anywhere where Ethicon conducted 10 their own safety studies in order to look as to 11 whether or not this amount of material was actually 12 necessary to support a woman's pelvic organs? 13 A. No. 14 Q. Did you see anywhere where Ethicon did any 15 clinical trials to determine whether or not the pore 16 sizes of Gynemesh PS were necessary to be that size 17 in order to support pelvic organ prolapse? 18 A. No. 19 Q. Did you see anywhere where Ethicon justified 20 or clinically studied that it was necessary for them 21 to have pores that would collapse and look like the 22 deformed pores on the DVD in order to be safely 23 implanted in a woman? 24 MR. THOMAS: Objection; argumentative.</p>	<p>1 A. It's healthy tissue in healthy rats. 2 Q. Is it being used with trocars and cannulas to 3 pull it in there? 4 A. No trocars. 5 Q. Is it going in through a transvaginal 6 incision of the rat? 7 A. No, nothing like this. 8 Q. Is it being permanently implanted in the 9 rat's tissue? 10 A. It's only implanted for 90 days. 11 Q. Were any forces placed on the mesh during the 12 implanting or being forced -- any forces on the mesh 13 after implantation? 14 A. No. When placing in the subcutaneous area, 15 you don't have any forces. 16 Q. Is the subcutaneous skin in the back of a rat 17 the same as the delicate pelvic tissues of a woman? 18 A. No. It is -- the tissue reaction of pure fat 19 is attenuated. 20 Q. When Prolift or any other pelvic organ 21 prolapse mesh is put into a woman's tissue, is that 22 because it's healthy or unhealthy? 23 MR. THOMAS: Objection. 24 THE WITNESS: Unhealthy.</p>
<p style="text-align: center;">Page 215</p> <p>1 BY MR. ANDERSON: 2 Q. Did you see that? 3 A. No. 4 Q. You were asked a whole lot of questions about 5 this 91-day rat study, so let's talk about a rat 6 study if we could. That was an internal Ethicon 7 study; correct? 8 A. Yes. 9 Q. Done by Ethicon scientists? 10 A. Yes. 11 Q. Was it peer-reviewed in the peer-reviewed 12 publications? 13 A. No. 14 Q. The size of the piece of mesh, can you just 15 show the jury what the size of the piece of mesh 16 would be that went into the back of these little 17 rats? 18 A. It's usually the size of the fingertip or the 19 nail. 20 Q. Okay. So we have a piece of mesh the size of 21 our fingernail going into the back of a rat for 91 22 days. That's what this study was; correct? 23 A. Yes. 24 Q. Is that going into healthy tissue?</p>	<p style="text-align: center;">Page 217</p> <p>1 BY MR. ANDERSON: 2 Q. And is it being permanently implanted or 3 implanted for 91 days? 4 A. It's permanently for years hopefully. 5 Q. And are these rats having sexual relations 6 while they have the mesh in their back? 7 MR. ANDERSON: I would like to withdraw that 8 question. 9 THE WITNESS: I think so. 10 BY MR. ANDERSON: 11 Q. Let me ask you this, Doctor. 12 Would it be safe to take a three-month study 13 of a piece of mesh that's the size of your fingernail 14 that was in the back of a rat where no trocars were 15 used in healthy tissue, not going through a 16 transvaginal incision, with no forces placed on the 17 mesh, in order to say this study will tell you that 18 Prolift can be safely implanted in a woman's vagina 19 for the rest of her life? 20 A. It would be very dangerous to take this study 21 as a proof for safety. This is not justified. And 22 if you'll remember to the results, there wasn't no -- 23 there wasn't a significant difference among the 24 meshes. Meanwhile, you have hundreds of studies</p>

Page 218	Page 220
<p>1 showing that the material has an impact on the tissue 2 ingrowth. So if you make your own study and seeing 3 no difference in these small group of animals, then 4 you should think of exchanging the people who are 5 responsible for this study. It is -- yeah.</p> <p>6 Q. So counsel asked you on cross-examination -- 7 he said, "You have not designed a device that was 8 designed for the -- for pelvic organ prolapse." Do 9 you remember that question?</p> <p>10 A. I remember it.</p> <p>11 Q. Has Ethicon ever designed a mesh that was 12 specifically designed for the pelvic floor?</p> <p>13 A. No.</p> <p>14 Q. You were asked three different questions that 15 I want to go to, Doctor. You were asked at the 16 beginning of your cross-exam, "91 percent of all 17 surgical meshes on the market today are made of 18 polypropylene." Do you remember that question?</p> <p>19 A. Yes.</p> <p>20 Q. And do you remember the question of, "Can you 21 think of any product on the market today that is 22 safer than Prolift for pelvic organ prolapse?" Do 23 you remember those questions?</p> <p>24 A. Yes.</p>	<p>1 C E R T I F I C A T E</p> <p>2</p> <p>3 I, Tami Cline, Registered Merit Reporter, 4 Certified Realtime Reporter, and Florida Professional 5 Reporter, do hereby certify that, pursuant to notice, 6 the deposition of PROF. DR. MED. UWE KLINGE was duly 7 taken on November 10, 2014, at 9:04 a.m. before me.</p> <p>8 The said PROF. DR. MED. UWE KLINGE was duly 9 sworn by me according to law to tell the truth, the 10 whole truth and nothing but the truth and thereupon 11 did testify as set forth in the above transcript of 12 testimony. The testimony was taken down 13 stenographically by me. I do further certify that 14 the above deposition is full, complete, and a true 15 record of all the testimony given by the said 16 witness.</p> <p>17</p> <p>18</p> <hr/> <p>19 Tami Cline, RMR, CRR, FPR</p> <p>20</p> <p>21 (The foregoing certification of this 22 transcript does not apply to any reproduction of the 23 same by any means, unless under the direct control 24 and/or supervision of the certifying reporter.)</p>
Page 219	Page 221
<p>1 Q. Is Prolift or Prolift+M still on the market 2 today?</p> <p>3 MR. THOMAS: Objection.</p> <p>4 THE WITNESS: So far I know, it is not longer 5 on the market.</p> <p>6 MR. ANDERSON: I don't have any other 7 questions.</p> <p>8 MR. THOMAS: We need to consult.</p> <p>9 THE VIDEOGRAPHER: We are off the record.</p> <p>10 The time is 2:01 p.m.</p> <p>11 (A recess was taken from 2:01 p.m. until 2:02 p.m.)</p> <p>12 MR. THOMAS: That's all the questions I have.</p> <p>13 (Whereupon, the deposition concluded at 14 2:02 p.m.)</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3</p> <p>4 Please read your deposition over carefully 5 and make any necessary corrections. You should state 6 the reason in the appropriate space on the errata 7 sheet for any corrections that are made.</p> <p>8</p> <p>9 After doing so, please sign the errata sheet 10 and date it. It will be attached to your deposition.</p> <p>11</p> <p>12 It is imperative that you return the original 13 errata sheet to the deposing attorney within thirty 14 (30) days of receipt of the deposition transcript by 15 you. If you fail to do so, the deposition transcript 16 may be deemed to be accurate and may be used in 17 court.</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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	Page 223	
1	ACKNOWLEDGMENT OF DEONENT	
2		
3	I, _____, do hereby	
4	acknowledge that I have read the foregoing pages, 1	
5	to 224, and that the same is a correct transcription	
6	of the answers given by me to the questions therein	
7	propounded, except for the corrections or changes in	
8	form or substance, if any, noted in the attached	
9	Errata Sheet.	
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12	_____	
13	PROF. DR. MED. UWE KLINGE	DATE
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18	Subscribed and sworn to before me this	
19	____ day of _____, 20____.	
20	My Commission expires: _____	
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22	_____	
	Notary Public	
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